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[1] IN THE CIRCUIT COURT OF THE 11TH
[2] JUDICIAL CIRCUIT IN AND FOR
[3] DADE COUNTY, FLORIDA
[4]
[5] HOWARD A. ENGLE, M.D., et al.
[6] vs. Case #94-08273CA (20)
[7] RJ REYNOLDS TOBACCO COMPANY,
[8] et al.
[9] May 21, 1998
[10] Richmond, Virginia
[11]
[12] The telephonic deposition of RICHARD P. SOLANA,
[13] Ph.D, a witness, taken at the instance of the
[14] Plaintiff, before Sherall W. Dementi, Notary Public
[15] for the State of Virginia at Large, beginning at 9:20
[16] a.m., at Hunton & Williams, 951 East Byrd Street,
[17] Richmond, Virginia; said deposition taken pursuant to
[18] the Rules of the Supreme Court of Virginia.
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[3] I N D E X
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[5] RICHARD P. SOLANA, Ph.D.
[6] BY MR. HOAG 4
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[12]
[13] NUMBER PAGE
[14] Plaintiff's Exhibit 1. 105
[15] Curriculum vitae of Richard P. Solana, Ph.D.
[16]
[17] RICHARD P. SOLANA, Ph.D, a Witness, called by the
[18] Plaintiffs, first being duly sworn, testified as
[19] follows:
[20]
[21] EXAMINATION BY MR. HOAG:
[22]
[23] Q State your name for the record, please.
[24] A Yes, Richard Solana.
[25] Q Mr. Hoag, I'm John Hoag, and I work with

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[1] Stanley Rosenblatt, special association, in Miami,
[2] Florida. You have been listed as a witness in the
[3] Engle case. Did you know you were listed as a witness
[4] in the Engle case?
[5] A Yes.
[6] Q How long have you known that?
[7] A Gosh, something in the order of weeks. I
[8] can't remember how long I have known it.
[9] MR. HOAG: Before we go further, I just want
[10] to say for the record that this deposition was
[11] scheduled for 9:00 a.m, and we were told, I don't
[12] know, maybe a day or two ago, who was being
[13] deposed wanted to switch it from Frank Daylor
[14] first to Rich Solano first, and we said okay.
[15] I called in at 9:00 to the 800 number I was
[16] given. It didn't work, and I find out it was a
[17] different number. I actually got the different
[18] number connected at 9:15, and no one was on other
[19] than me. And I realize that's just a glitch that
[20] happens to everyone, but I just wanted to make a
[21] record that we were available to start at 9:00.
[22] I requested a resume or CV from both of the
[23] witnesses. To my knowledge we have not received
[24] them. I called Mr. Nunley and I left a message
[25] with Mr. Nunley directly, I spoke to him and told

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[1] him I needed the resumes if they were available.
[2] He did fax me a resume of what exists for
[3] Mr. Daylor, which is one page, which I have now.

[4] I asked for the same thing for Mr. Solana
[5] yesterday. I still haven't received that yet.
[6] Defense counsel representing Mr. Solana tells me
[7] that he believes that some kind of a resume of
[8] Mr. Solana was faxed to my office in Miami a
[9] couple of days ago, but I don't have that. There
[10] may have been some kind of problem with that
[11] being faxed over. I don't know one way or the
[12] other. It's one of those things kind of like the
[13] 800 number glitch.

[14] Be that as it may, I am starting the
[15] deposition without a copy of his resume.
[16] Hopefully that will be faxed to me.

[17] MR. BHATIA: It's my understanding it's been
[18] faxed.

[19] MR. HOAG: I already said that on the
[20] record. I don't think we need to put any more
[21] on.

[22] MR. BHATIA: No, no. I just want to make my
[23] little record. It will be very short. We were
[24] on the call at 9:15. It's now 9:20 by my watch,
[25] and I know we have been on the phone waiting to

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[1] get started for at least the last ten minutes.
[2] We are prepared to begin. The witness does have
[3] an engagement at 12:15. The order of the
[4] witness was switched to accommodate the
[5] witness' attendance at his daughter's graduation.
[6] And we would hope that counsel could accommodate
[7] the witness. Let's get started.

[8] Q Have you ever been deposed before?

[9] A No, I have not.

[10] Q Now, you understand that at a deposition
[11] that there's a court reporter present with you, and
[12] the court reporter is going to take down everything
[13] you say and all the questions that I ask, correct?

[14] A Yes.

[15] Q If at any time I say something that you
[16] don't understand, let me know, and I will try to
[17] rephrase it or repeat it. Okay?

[18] A Yes.

[19] Q And you need to make sure when I ask you a
[20] question that you give me a verbal response. Of
[21] course, a nod of the head I can't see it over the
[22] phone and the court reporter can't type it down
[23] because it's not a verbal response. You understand
[24] that, correct?

[25] A Yes, sir.

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[1] Q At any time you need to take a break, let me
[2] know and we can provide you time to do so.

[3] A Thank you.

[4] Q Now, if you can briefly describe for me your
[5] educational background beginning with college.

[6] A Yes, I've got a Bachelor's Degree in 1972
[7] from the Air Force Academy. I have got a degree in
[8] Doctor of Veterinary Medicine from 1977 from Cornell
[9] University, and a Ph.D. in toxicology from Medical
[10] College of Virginia in 1986.

[11] Q Can you briefly describe for me your
[12] employment history.

[13] A Yes, starting when?

[14] Q Starting with the first time you were
[15] employed from the age of 18 on.

[16] A All right. Well, I was at the Air Force
[17] Academy from 17 until 21. Then I spent the next 21
[18] years in the service, the first ten or eleven in the
[19] air force and the next eleven in the army. Would you
[20] like me to try to recall the individual assignments
[21] during that time?

[22] Q Yes.

[23] A From 1972 to '73, I was a personnel officer
[24] in the Air Force; '73 to '77, I was at Cornell
[25] Veterinary College; '77 to '80, I was working as a

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[1] veterinarian in Syracuse, New York for the air force;
[2] '80 to '82, I was working as a veterinarian for the
[3] air force in Ankara, Turkey, and the title of that was
[4] Chief of Public and Environmental Health.

[5] And then in 1982, I switched to the army and
[6] I spent the year in Frederick, Maryland, Fort Detrick,
[7] at the US Army Medical Bioengineering Research and
[8] Development Laboratory as a Special Projects Officer.
[9] 1983 to 1986, I was at the Medical College of Virginia
[10] getting my Ph.D. And then 1986 to 1989 -- 1986 to
[11] 1993 when I retired from the army, I was at the US
[12] Army Medical Research Institute of Chemical Defense at
[13] Aberdeen Proving Ground, Maryland, and my jobs there
[14] were first Chief of Applied Pharmacology Branch and
[15] then Chief of the Pharmacology Division, and I spent a
[16] period of time as an acting Deputy Commander of the
[17] laboratory. And a couple of additional
[18] responsibilities during that time were being
[19] consultant to the Army Surgeon General and a delegate
[20] to the US-Soviet Negotiations on Destruction and
[21] Non-Production of Chemical Weapons.

[22] Starting in 1993, I came to Philip Morris,
[23] retired from the service, and worked as an Associate
[24] Principal Scientist, and then in 1997, last year, I
[25] became the Director of Product Integrity. And that's

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[1] the present.

[2] Q Okay. In 1982, you said you were on some
[3] special project?

[4] A No. The title was Special Projects Officer.

[5] Q What were your duties there?

[6] A Well, the responsibilities there, as best as
[7] I can remember -- that was at the US Army Medical
[8] Bioengineering Research and Development Laboratory,
[9] and I was working on various toxicology projects and
[10] contracts, looking at various smokes and obscurants
[11] that the army was considering using, and items that
[12] had to do with chemical weapons systems, and
[13] evaluating them for various toxicology and end points.

[14] Q Prior to the time that you went to work for
[15] Philip Morris, had you done any work at all on
[16] cigarettes or cigarette smoke?

[17] A No.

[18] Q You talked about smoke and obscurants. What
[19] do you mean when say smoke and obscurants?

[20] A Well, the army has at times they will use
[21] devices which generate smoke and obscurant smoke, sort
[22] of the same category, to hide their soldiers. So
[23] those are really what I'm talking about with both
[24] terms.

[25] Q Now, during the time that you were in the

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[1] A If we had a material that we were
[2] considering as a candidate for whatever the project
[3] was trying to develop, you know, various chemicals
[4] might be candidates, and when you are going to do
[5] testing on them, one of the first things you want to
[6] know exactly is what that chemical is, so you test it
[7] to prove its identity, that it is in fact what it is
[8] said to be in its purity, to prove that it is in fact
[9] it is supposed to be.

[10] Q So you test chemicals to see if they are
[11] what they are supposed to be; is that basically all
[12] you did with the chemicals, or did you do anything
[13] more than that?

[14] A Well to test -- well, I think I'm a little
[15] confused by the question. You had asked if I did
[16] chemical analysis, I believe, on chemicals, and now
[17] you are saying testing chemicals. Once we have
[18] identified the chemical, there are tests other than
[19] chemistry, such as when I talked about the smokes and
[20] obscurants where we do various toxicology end points
[21] on these smokes, you can consider these smokes as
[22] chemicals, and we might do various toxicity tests on
[23] them. Those wouldn't be chemistry tests, but they
[24] would be tests on chemicals.

[25] Q When you say toxicology end points, what are

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[1] military, it sounds like it was from 1972 until 1993,
[2] is that correct, it was from 1972 to 1993 you were in
[3] the military?

[4] A Well, I was commissioned as an officer in
[5] 1972. Actually I started in the military when I
[6] entered the Air Force Academy in 1968.

[7] Q How old were you then? Well, what's your
[8] date of birth? Let me put it that way.

[9] A March 24, 1951.

[10] Q So when you entered the military academy,
[11] that was like your first year of college; is that
[12] right?

[13] A That's right. That was my first year of
[14] college.

[15] Q So from the time you started your first year
[16] of college from 1968 to 1993, you were in the
[17] military?

[18] A Yes, sir.

[19] Q Did you ever analyze the chemical
[20] composition of any substance while you were in the
[21] military?

[22] A Yes. There would be times when that would
[23] be necessary.

[24] Q What is an example of when that was
[25] necessary?

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[1] you talking about?

[2] A It could be anything. It could be a
[3] short-term testing in rats; could be evaluation with
[4] cells in culture to look at the genotoxicity; could be
[5] neurotoxicology, reproductive toxicology; various
[6] typical battery of end points that might be evaluated
[7] in toxicology.

[8] Q Why did you decide to retire from the
[9] military?

[10] A Because I was eligible.

[11] Q What was your rank at the time you retired?

[12] A Lieutenant colonel.

[13] Q Do you have to retire or was it your choice?

[14] A No. It was my choice. I had several good
[15] job offers in the service.

[16] Q Since you had several good job offers in the
[17] service, what was the reason you decided not to take
[18] those?

[19] A I was looking forward to not having to move
[20] my family anymore.

[21] Q How did you come to work for Philip Morris?

[22] A I was interviewing at various companies and
[23] had been talking with a person was working at Philip
[24] Morris, a toxicologist at Philip Morris, who was also
[25] my advisor when I got my Ph.D. I knew him before he

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[1] came to Philip Morris.
 [2] Q What's his name?
 [3] A Dr. Richard Carchman.
 [4] Q You said Dr. Carchman was your advisor --
 [5] just to make sure I'm understanding -- Dr. Carchman
 [6] was you advisor during the time you got your Ph.D, and
 [7] at the time, he didn't work for Philip Morris either?
 [8] A That's correct.
 [9] Q So about what year did he talk to you about
 [10] the possibility of working for Philip Morris, if I'm
 [11] understanding you correctly?
 [12] A Well, as you know, I retired in 1993, and I
 [13] had been spending the last year or so, a little bit
 [14] for than that, looking at job opportunities, and had
 [15] always talked to him as a friend for advice. So he
 [16] knew I was looking. And shortly before, maybe even
 [17] the last six months before I retired, an opening
 [18] became available, and he called me and asked me if I
 [19] was interested.
 [20] Q And what was the opening?
 [21] A The job that I took as Associate Principal
 [22] Scientist, working for him.
 [23] Q What did he tell you about the job?
 [24] A That it would be involved in evaluating
 [25] ingredients and changes to cigarettes.

[1] A Gosh, I couldn't give you an estimate. I
 [2] could tell you that it was probably of a period of
 [3] months that I was experimenting with both pipes and
 [4] cigarettes and decided I liked the pipe better.
 [5] Q And why did you decide you liked the pipe
 [6] better?
 [7] A Partly because I have a sweet tooth, and
 [8] pipe tobacco, much of it tastes much sweeter. Pipe
 [9] smoke is much sweeter. And I like pipes. The wood is
 [10] pretty.
 [11] Q How often do you smoke a pipe?
 [12] A That varies a lot. I can go for long
 [13] periods of time where I smoke several bowls a day
 [14] constantly for years, and I've gone equal stretches of
 [15] time where I haven't smoked it at all, and I've gone
 [16] times when smoke it once a month. It totally varies.
 [17] Q Do you smoke the pipe now?
 [18] A Yes.
 [19] Q How frequently?
 [20] A I know in the last two years, it's varied.
 [21] Probably more like everything from a couple times a
 [22] week to once a month probably is the range. It's
 [23] usually a function of how busy I am.
 [24] Q What do you mean? Which way does it work;
 [25] the busier you are, the less you smoke or the more you

[1] Q Told you it would be involved in evaluating
 [2] ingredients and changes in cigarettes.
 [3] A Correct, proposed new ingredients and
 [4] proposed cigarette design changes would be a clear way
 [5] to say it.
 [6] Q Did he give you some idea what those new
 [7] ingredients and new design changes were or would be?
 [8] A No. That wouldn't have been possible. I
 [9] wasn't an employee, and those would be trade secrets.
 [10] Q At the time he was talking to you prior to
 [11] the time you worked for Philip Morris, did you have
 [12] any idea what ingredients were in cigarettes?
 [13] A No.
 [14] Q Are you a smoker?
 [15] A I smoke a pipe.
 [16] Q Have you ever smoked anything other than a
 [17] pipe?
 [18] A Yes, when -- yes, I have.
 [19] Q What?
 [20] A I tried cigarettes about the time I was also
 [21] trying a pipe the first time.
 [22] Q How about how old were you?
 [23] A I guess I was 19, in college.
 [24] Q And about how many cigarettes did you smoke
 [25] when you were 19?

[1] smoke?
 [2] A The more I have time to take it easy, the
 [3] more I smoke. The more busy I am, you know, how do
 [4] you hold on to a pipe and run around and work? It's
 [5] difficult.
 [6] Q Is smoking a pipe safer than smoking
 [7] cigarettes in your opinion?
 [8] A I don't know that you can compare the two in
 [9] that way. I'm not sure what you mean.
 [10] Q You don't know what I mean by "safer"?
 [11] A What exactly are you trying to -- what end
 [12] point there? Could you define it for me, please.
 [13] Then I will be glad to answer.
 [14] Q What end point?
 [15] A Yes.
 [16] Q Just an honest answer from you. Do you know
 [17] what the word "safer" means?
 [18] A It can mean a lot of things technically.
 [19] Q What does it mean to you?
 [20] A Excuse me? You had broken up on that.
 [21] Q Okay. What does it mean to you?
 [22] A The word "safer"?
 [23] Q Yes. As it applies to cigarette smoking,
 [24] what does that word mean to you?
 [25] A I guess I would have to interpret it -- I

<p>Page 17</p> <p>[1] think that the typical interpretation would be the</p> <p>[2] risks associated with it as far as heart disease and</p> <p>[3] cardiovascular disease.</p> <p>[4] Q So by your definition of safer, in your</p> <p>[5] opinion is pipe smoking safer than cigarette smoking?</p> <p>[6] A I don't know.</p> <p>[7] Q In your opinion is it dangerous to smoke</p> <p>[8] cigarettes?</p> <p>[9] A Clearly there's a risk factor of several</p> <p>[10] diseases related to cigarettes.</p> <p>[11] Q So in your opinion is it dangerous to smoke</p> <p>[12] cigarettes?</p> <p>[13] A In my opinion, my honest opinion is that</p> <p>[14] anything in moderation is acceptable.</p> <p>[15] Q Are you saying in your opinion that it is</p> <p>[16] not dangerous in moderation to smoke cigarettes?</p> <p>[17] A Yes.</p> <p>[18] Q And what do you call moderation?</p> <p>[19] A I don't have a clear definition of</p> <p>[20] moderation, but clearly in anything, as I said,</p> <p>[21] whether it's how fast you drive a car, or smoking, or</p> <p>[22] drinking, you know, moderation of some sort is,</p> <p>[23] however that might be interpreted by an individual is</p> <p>[24] acceptable.</p> <p>[25] Q Would you consider smoking five cigarettes a</p>	<p>Page 18</p> <p>[1] day being moderation?</p> <p>[2] A Probably yes.</p> <p>[3] Q How about about ten cigarettes; would you</p> <p>[4] consider smoking ten cigarettes a day to be</p> <p>[5] moderation?</p> <p>[6] A It's possible.</p> <p>[7] Q How about 20 cigarettes?</p> <p>[8] A I suppose that now you're in the average,</p> <p>[9] and that's also possibly moderation. But I don't put</p> <p>[10] a hard number on moderation. I think it's an</p> <p>[11] individual choice.</p> <p>[12] Q So as long as someone smokes moderately, you</p> <p>[13] don't consider smoking to be a dangerous activity,</p> <p>[14] correct?</p> <p>[15] A Yes.</p> <p>[16] Q And what do you base that on?</p> <p>[17] A Well, you had asked me my person opinion,</p> <p>[18] and that is my personal opinion. It's not a</p> <p>[19] scientific one.</p> <p>[20] Q Well, you are a toxicologist, right?</p> <p>[21] A Yes.</p> <p>[22] Q You are very familiar with the contents of</p> <p>[23] cigarettes and cigarettes smoke, aren't you?</p> <p>[24] A Yes.</p> <p>[25] Q Based on your understanding of the contents</p>
<p>Page 19</p> <p>[1] of cigarettes and cigarette smoke, why do you believe</p> <p>[2] that moderate smoking is not a dangerous activity for</p> <p>[3] the smoker?</p> <p>[4] A As you said, I'm a toxicologist, and one of</p> <p>[5] the key premises of toxicology is that dose is the key</p> <p>[6] factor. So that's a very good parallel, actually, to</p> <p>[7] my personal concept of moderation, that anything has</p> <p>[8] its level at which it's acceptable.</p> <p>[9] Q Anything has a level at which it's</p> <p>[10] acceptable; is that what you just said?</p> <p>[11] A Yes.</p> <p>[12] Q So what leads you to the conclusion that</p> <p>[13] there is some safe dose of cigarette smoke that a</p> <p>[14] smoker can inhale?</p> <p>[15] MR. BHATIA: Objection to the form of the</p> <p>[16] question.</p> <p>[17] Q What leads you to the conclusion that there</p> <p>[18] is some safe dose of cigarette smoke that a smoker can</p> <p>[19] inhale?</p> <p>[20] MR. BHATIA: Same objection.</p> <p>[21] A I didn't make a conclusion that there was</p> <p>[22] some safe dose.</p> <p>[23] Q In your opinion is there a safe dose of</p> <p>[24] cigarette smoke that a smoker can inhale?</p> <p>[25] A When we were talking about safe before, I</p>	<p>Page 20</p> <p>[1] told you that it was a matter of clearly</p> <p>[2] characterizing what you meant when you're talking</p> <p>[3] about safe, and that it's clear in my mind that</p> <p>[4] smoking is risk factor for things such as lung cancer</p> <p>[5] and heart disease.</p> <p>[6] Q In your opinion does smoking -- in the</p> <p>[7] entire history of the United States, has smoking ever</p> <p>[8] resulted in the premature death of anyone due to</p> <p>[9] smoking and inhalation of smoke into the lungs?</p> <p>[10] A Could you repeat it.</p> <p>[11] Q In your opinion has smoking cigarettes, and</p> <p>[12] by that I mean the inhalation of cigarette smoke into</p> <p>[13] the lungs, has that activity ever resulted in the</p> <p>[14] premature death of anyone?</p> <p>[15] A I honestly don't know. The data -- there's</p> <p>[16] much data -- I hate to repeat myself, but I think it's</p> <p>[17] the right answer -- there is much data, epidemiology</p> <p>[18] data that shows that it's clearly a risk factor in</p> <p>[19] certain diseases, that's clear. But that data talks</p> <p>[20] about populations. You are asking about individuals,</p> <p>[21] and I have no way of knowing that.</p> <p>[22] Q I'm not talking about a particular</p> <p>[23] individual when I asked the question. When I say in</p> <p>[24] your opinion, I mean is out of all the people that</p> <p>[25] have ever smoked cigarettes in the United States, in</p>

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[1] your opinion has any one of those people ever died
[2] prematurely as a result of having smoked and inhaled
[3] cigarettes into their lungs?

[4] A Two things. One is, I -- again, it doesn't
[5] matter that it's not a particular individual, I still
[6] really don't know. But also, it's, you know, when it
[7] comes to my technical responsibilities, they have to
[8] do with evaluating changes in cigarette designs and
[9] additives to ingredients, and I can't tell you that I
[10] have followed all that literature closely.

[11] Q When you say that literature, what
[12] literature are you referring to?

[13] A Well, you were asking about people dying
[14] from smoking, and I assume you are talking about
[15] epidemiology and that kind of thing. Clearly it's not
[16] literature that has to do with evaluation of cigarette
[17] designs and ingredients.

[18] Q Have you ever read any newspaper articles,
[19] magazine articles, or anything in the media concerning
[20] cigarette smoke and health?

[21] A Yes.

[22] Q Based on everything you have ever read or
[23] seen and all the information you've accumulated during
[24] the time you had your Ph.D, and all the information
[25] you've accumulated since you worked for Philip Morris,

[1] Q Risk factor and cause, are those the same
[2] thing to you?

[3] A No.

[4] Q I didn't ask you about risk factor. I asked
[5] you in your opinion is it more likely than not that
[6] cigarette smoking causes lung cancer?

[7] A I understand that you used the word "cause."
[8] The way I was interpreting is you said more likely
[9] than not, and that to me is more talking about the
[10] risk, not just the word cause alone. If you want to
[11] change the question to does it cause it, then I guess
[12] I would repeat my other answer that I think cause and
[13] effect, yeah, has not absolutely been proven, because
[14] there's a lack of reproducible definitive animal
[15] studies.

[16] Q You personally don't know whether or not
[17] cigarette smoking causes lung cancer; is that correct?

[18] A This is personally or as a scientist?

[19] Q Personally. You personally do not know
[20] whether cigarette smoking causes lung cancer, correct?

[21] A That's correct. I cannot make that absolute
[22] statement that it is a cause.

[23] Q And as a scientist you do not know whether
[24] or not cigarette smoking causes lung cancer, correct?

[25] A That's correct. I cannot make an absolute

[1] do you have an opinion as to whether or not cigarette
[2] smoking causes any disease?

[3] A Yes. I very much believe that cigarette
[4] smoking has been well shown to be a risk factor for
[5] heart disease, for lung cancer, for some other
[6] diseases. But to say -- your question was is there
[7] data to show that it causes it, and I think one of the
[8] typical pieces of data that is usually used to prove
[9] cause and effect is some reproducible animal studies,
[10] and those I have not yet seen to exist.

[11] Q So what is your opinion as the whether or
[12] not cigarette smoking causes any disease?

[13] A That clearly is a risk factor, but the
[14] scientific data is not complete enough to make an
[15] absolute statement that there's a cause and effect
[16] relationship.

[17] Q Is it more likely than not that cigarette
[18] smoking causes cancer in your opinion?

[19] A Is it more likely than not?

[20] Q That cigarette smoking causes lung cancer?

[21] A Well, I guess that comes back again, I
[22] guess, to the fact that it is a risk factor, and
[23] epidemiological has shown to be a risk factor for lung
[24] cancer. So the numbers on those are higher than not
[25] smoking.

[1] statement that it is a cause.

[2] Q And personally you don't know whether or not
[3] cigarette smoking causes any disease; is that correct?

[4] A That's broader, and I would have to just say
[5] that since I don't review all that literature, I can't
[6] say that I'm knowledgeable enough about all of it to
[7] say absolutely. But as far as what I have seen,
[8] without making an effort to look at it all, I would
[9] have to give you the same answer, that's correct.

[10] Q As a scientist you don't know whether or not
[11] cigarette smoking causes any disease, correct?

[12] A No. Was that the same question as the one
[13] before?

[14] Q One was personally. Now I'm asking you as a
[15] scientist you don't know whether cigarette smoking
[16] causes any disease?

[17] A Right, same answer.

[18] Q Has there ever been a time in your life that
[19] you knew whether or not cigarette smoking caused any
[20] disease?

[21] A This is a -- has there ever been a time in
[22] my life that I knew?

[23] Q Right. Did you know when you were 20 or 30?
[24] Was there ever a time when you knew cigarette smoking
[25] causes any disease?

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[1] A Not in an absolute sense judging it by --
[2] having learned about science and become a Ph.D. since
[3] I was 20 and becoming a veterinarian since I was 20,
[4] and knowing something about science and literature,
[5] against that standard, no, there was never a time in
[6] my life I knew.

[7] Now, if you want to say against a layman's
[8] standard of did I read something that told me it was
[9] true and I just accepted it because I was told it,
[10] yes, you'd read warning packs and whatnot, and the
[11] warning labels say various things about what it
[12] causes, and as a layman you would say, okay, well it
[13] says it causes this, and so it does.

[14] Q So you did accept that, and you do accept
[15] the warning label that says cigarette smoking causes
[16] lung cancer, heart disease, and emphysema?

[17] A I did accept that at that time, that's
[18] right.

[19] Q At what point did you accept that?

[20] A As I said, prior to getting involved in
[21] the -- well, advanced medical and scientific training
[22] where I could critically review it, up until that
[23] point.

[24] Q About what year would that have been?

[25] A Well, I guess, as I said before, I went to

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[1] Cornell for veterinary medicine from 1973 to 1977, so I
[2] would have been around that time I would have been
[3] learning enough to be able to critically review it,
[4] and even more so during my Ph.D. from '83 to '86.

[5] Q So are you saying prior to 1973 you had
[6] accepted whatever was on the warning label of the
[7] cigarette package as being accurate.

[8] A Can you repeat the question.

[9] Q Are you saying that prior to 1973, you had
[10] accepted whatever was on the warning label of a
[11] cigarette package as being accurate?

[12] A Yes.

[13] Q But after 1973 you did not accept it as
[14] being accurate?

[15] A Well, I don't know when after I started my
[16] education. I said -- yes, I don't know when after I
[17] started my education. As I said, during that
[18] education process, and it was from '73 to '77 and '83
[19] to '86, plus all my involvement working in those
[20] areas, somewhere along that line, but I can't tell you
[21] exactly when.

[22] Q Do you know what was on the cigarette label
[23] in 1972?

[24] A I'm not sure whether it was on the cigarette
[25] pack or newspaper articles or whether it was on

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[1] advertising or where I read it, but it was clearly
[2] information that was provided in some form.

[3] Q So were you familiar at all with the 1964
[4] Attorney General's report on smoking and health?

[5] MR. BHATIA: You mean you mean the Surgeon
[6] General's Report?

[7] Q Surgeon General's report on smoking and
[8] health?

[9] A Specifically that document, no. If you mean
[10] by familiar had I read any of it, no.

[11] Q And as we sit here today have you ever read
[12] any of it?

[13] A Bits and pieces of it, yes.

[14] Q Do you recall whether you read any newspaper
[15] reports about the 1964 Surgeon General's report?

[16] A I honestly can't say that I remember 20 or
[17] 30 years ago whether I recall reading something about
[18] the report. It wouldn't surprise me if I had, but I
[19] can't recall it.

[20] Q One of the conclusions of that report is
[21] that cigarette smoking causes lung cancer, right?

[22] A Yes.

[23] Q As we sit here today, you disagree with that
[24] time conclusion, correct?

[25] A That's correct, although I accept the fact

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[1] that it is a risk factor.

[2] Q Did you switch or did you decide to smoke a
[3] pipe because of concerns about the health consequences
[4] of smoking cigarettes?

[5] A No. As I told you, I chose to smoke a pipe
[6] because the taste of the smoke is much sweeter and the
[7] handling of the pipe and the different finishes of the
[8] wood is what I like. In fact, I went through a whole
[9] lot of pipe tobaccos to find the one that I really
[10] liked the taste of, and I tended towards the more
[11] sweeter of all the pipe tobaccos.

[12] Q Now, you told me that you have known for a
[13] few weeks that you have been listed as a witness in
[14] the Engle case, correct?

[15] A Yes.

[16] Q Do you know whether you are listed as a
[17] witness in any other cases?

[18] A I don't think so.

[19] Q How did you come to find out you were a
[20] witness in the Engle case?

[21] A I was called by an attorney.

[22] Q Who?

[23] A I believe it was Cynthia Hughes Kuntz.

[24] Q Who does she work for?

[25] A Shook, Hardy & Bacon,

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[1] Q And what happened during that conversation?

[2] MR. BHATIA: I'm going to object to any

[3] attorney discussions. So if there's a substance

[4] of an attorney-client communication, please don't

[5] disclose it and maintain the privilege.

[6] Q In other words at the time you first

[7] received the call and you had never spoken to her --

[8] well, had you ever spoken to Cynthia Hughes Kuntz by

[9] the time she called you about whether you would be a

[10] witness?

[11] A Prior to the time she called me to be a

[12] witness in this case?

[13] Q Yes.

[14] A Yes.

[15] Q She had spoken to you prior to that?

[16] A Yes.

[17] Q About things other than being a witness in

[18] any case?

[19] A No. It was always about being a witness in

[20] a case.

[21] Q Was it always about being a witness in the

[22] Engle case?

[23] A No.

[24] Q So you had prior discussions about the

[25] possibility of being a witness in other cases prior to

[1] of any other case where you are listed as a witness?

[2] A As I said, I wasn't sure that I was still

[3] listed as a witness in any case, maybe I am. So no, I

[4] cannot recall.

[5] Q When you say still, what cases did you at

[6] one time believe you were a witness?

[7] A Well, there were -- huh. I guess I'm not --

[8] it's hard for me to answer, because I'm not sure what

[9] listed as a witness means as compared to -- the way I

[10] always looked at it was I was told that I would

[11] probably would have to be deposed. I'm assuming that

[12] means listed as a witness.

[13] MR. BHATIA: John, I think maybe the

[14] confusion is that he's talking about being called

[15] for deposition and the deposition canceling as

[16] opposed to being listed as a potential witness

[17] for trial. Maybe you guys are talking about two

[18] different things.

[19] A I apologize. I'm not comfortable with the

[20] terminology.

[21] Q You understand that you would have to be

[22] listed as a witness before you would be deposed; do

[23] you understand that?

[24] A Okay. I do now.

[25] MR. BHATIA: I'm not sure that's right. I

[1] being contacted to being a witness in Engle; is that

[2] correct?

[3] A Yes, sir.

[4] MR. BHATIA: I think he is listed in other

[5] cases, John. He is on the witness list in other

[6] cases.

[7] MR. HOAG: I guess he doesn't know that.

[8] Q Before the attorney just told you that he

[9] thinks you are a witness in other cases, did you know

[10] you were?

[11] A I've been called -- I honestly can say I

[12] don't keep track, but I have been called to be a

[13] witnesses in some cases and that has fallen through,

[14] and I'm told which ones, and it comes to pass and it

[15] doesn't. When the day comes for the deposition as it

[16] has today, I get deposed. If I'm a witness, I may

[17] have been told and I just haven't bothered to keep

[18] track of it.

[19] Q Approximately when were you first contacted

[20] about the possibility of being a witness in any

[21] tobacco case?

[22] A Oh gosh, sometime in the last -- I'm going

[23] to really guess and say six months, four to six

[24] months. I'm not really sure.

[25] Q Other than Engle can you think of the name

[1] think you can depose whoever you want, where they

[2] are listed as witnesses or not, but go ahead.

[3] MR. HOAG: You mean we can depose any of

[4] your people right now?

[5] MR. BHATIA: Unless Florida has some

[6] different rule.

[7] Q Well, you had depositions scheduled and then

[8] canceled; is that correct?

[9] A Yes, that's correct.

[10] Q What cases?

[11] A I believe one was New York, and I can't

[12] remember what the name of the case was. And there was

[13] one other -- there might have been two others, but I

[14] honestly don't remember the names of them.

[15] Q Do you know why those depositions were

[16] canceled?

[17] A No, I don't.

[18] Q Who canceled them?

[19] A I don't know. I would get a call telling me

[20] that I was going to be deposed and then have it

[21] canceled. I don't know who made the decisions.

[22] Q Now, there is a thing called Fact Witness

[23] Designations of Defendant Philip Morris Incorporated.

[24] Have you seen that, your fact witness designation?

[25] A I'm not sure what that is.

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[1] Q Well, it has your name, case number 29 on
[2] it, and it says, underneath your name it says "This
[3] witness may testify concerning various aspects of
[4] research and development." That's all it says.

[5] A Okay.

[6] Q So my question to you is what aspects of
[7] research and development are you going to testify
[8] about?

[9] A Well, I can tell you what my
[10] responsibilities are, if that's what you are asking.
[11] My responsibilities are all I am really knowledgeable
[12] about.

[13] Q And your responsibilities are specifically
[14] related to aspects of research and development,
[15] correct?

[16] A Research and development is very broad, but
[17] yes, some aspects of research and development are what
[18] I'm responsible for.

[19] Q And what aspects of research and development
[20] have you ever been responsible for?

[21] A I am currently responsible as the Director
[22] of Product Integrity for evaluating any proposed new
[23] ingredient or changes in cigarette design to determine
[24] whether they are acceptable for use in new cigarettes.
[25] And a large majority of my time at Philip Morris

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[1] better to be complete. When I say proposed new
[2] ingredients and cigarette design changes, the details
[3] there might be not only ingredients in part of the
[4] cigarette or the packaging material but also changes
[5] in the levels of the ingredients that might requested.
[6] Or the new cigarette design changes might be a design
[7] change of a conventional cigarette or it might be
[8] something like the new electrically heated cigarette
[9] would be a new design. And along with that area of
[10] expertise, we also support issues pertinent to our
[11] knowledge that have to do with factory incidences or
[12] consumer complaints, that kind of thing.

[13] Q You say that's an area of expertise for you?

[14] A Well, dealing with ingredients in cigarette
[15] design and doing the reviews for it gives us the
[16] ability -- to review the ingredients, we have to know
[17] what they are, therefore we have the information
[18] provide when a list of ingredients is required. So
[19] therefore that would be an additional part of our
[20] responsibility based on that.

[21] Q You understand you are not listed as an
[22] expert witness; you know that, right?

[23] A Yes, that's right.

[24] Q You are just listed as a fact witness?

[25] A Yes.

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[1] really has focused -- I've always from the time I
[2] arrived have worked on that kind of thing. Very
[3] little responsibility outside of that. Mostly just
[4] reading of other documents.

[5] When I first arrived, I spent a couple weeks
[6] reading the EPA report on ETS, but after that I really
[7] didn't do anything in the ETS area. So my focus
[8] really has been in the areas that I mentioned as my
[9] current responsibilities.

[10] Q So basically it boils down to evaluating a
[11] proposed or new ingredient in cigarettes; is that
[12] right?

[13] A Could you say it again.

[14] Q Proposed or new ingredients in cigarettes,
[15] their evaluation, that's pretty much all there is to
[16] it, right?

[17] A Proposed new ingredients or cigarette design
[18] changes.

[19] Q Anything else?

[20] A That pretty much covers it's all.

[21] Q This would be proposed new ingredients
[22] and/or cigarette design changes from 1993 forward; is
[23] that correct?

[24] A Yes, since I arrived, that would be my
[25] responsibility. Now, does that -- maybe it would be

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[1] Q Is that correct?

[2] A Yes.

[3] Q Do you know the difference between a fact
[4] witness and an expert witness?

[5] A Go ahead and explain it to me.

[6] Q No, I asked you if you knew the difference?

[7] A Oh, I'm sorry. I think I do.

[8] Q What is your understanding of the
[9] difference?

[10] A That a fact witness is responsible for
[11] providing answers to requests, you know, questions
[12] about the information of which they know something,
[13] and an expert witnesses is somebody who is, I guess,
[14] considered an expert in a broad area of responsibility
[15] and can speak to the whole thing. I'm not sure that
[16] really is very complete.

[17] MR. BHATIA: I am going to just interpose
[18] belatedly an objection to the form. I'm not sure
[19] the witness knows the distinction under Florida
[20] law between an expert and a fact witness or any
[21] other law for that matter, but go ahead, John.

[22] Q What facts do you know about the proposed
[23] new ingredients?

[24] A I'm sorry, about what proposed new
[25] ingredients?

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[1] Q Whatever proposed new ingredients you know
[2] about. What personal knowledge or facts do you have?

[3] MR. BHATIA: Objection to the form.

[4] Q What do you know?

[5] MR. BHATIA: That's pretty broad. Object to
[6] the form.

[7] MR. HOAG: I'm just basing it on what's in
[8] your disclosure statements.

[9] A Let me try to respond in some way. We, in
[10] the group that I'm responsible for, will review any
[11] new ingredient, and as I told you, use of the
[12] ingredient, any new cigarette design change that is
[13] proposed in R & D, and do whatever testing and
[14] evaluations are required for those. That is what we
[15] spend our day doing.

[16] So we have a group of people that all day
[17] every day are doing that. And I told you I've been
[18] doing it for five years. And so your question sort of
[19] asks me to summarize everything that everybody's been
[20] doing ever since I arrived.

[21] Q That's true. What are the new ingredients
[22] that you have evaluated since you have been at Philip
[23] Morris?

[24] A What are the new ingredients. There are a
[25] constant flow of them that are considered, and many of

[1] about the subject. To the extent that all you
[2] have given us is one sentence describing what he
[3] will talk about as a fact witness, and I'm asking
[4] questions related to that one sentence, again,
[5] I'll move to strike, because he can't answer the
[6] question.

[7] MR. BHATIA: I'm going to talk now.

[8] MR. HOAG: Go ahead.

[9] MR. BHATIA: The record will be clear that
[10] was not the question you put to him. The
[11] question you put to him was to list every
[12] ingredient that he has tested, and then you asked
[13] questions as broad as what do you know. Those
[14] questions, I think, are clearly objectionable.
[15] If you ask the witness proper questions, he will
[16] answer them.

[17] MR. HOAG: I'm also going to object to the
[18] facts disclosure which merely says "This witness
[19] may testify concerning various aspects of
[20] research and development" is so overly broad and
[21] vague as to be meaningless.

[22] Now, I'm going to ask my question again.

[23] Q What ingredients have you been involved in
[24] evaluating since you have been working at Philip
[25] Morris?

[1] them are, you know, reviewed by individuals that work
[2] for me, and if they require my attention, I look at
[3] them, if they don't require my attention, I don't look
[4] at them. So it's just not possible for me to list for
[5] you, you know, something that might be quite a long
[6] list. I can't recall all the ingredients that we have
[7] reviewed.

[8] MR. HOAG: Okay. To the extent the witness
[9] cannot answer the question in the ingredients, I
[10] am going to move to strike any testimony that he
[11] may have at trial regarding ingredients.

[12] MR. BHATIA: Do what you want. I'm going to
[13] tell you, I plan to ask the witness questions. I
[14] mean if you can't put a proper question to the
[15] witness, it's not my fault. Put something to him
[16] other than what do you know.

[17] MR. HOAG: The ingredients that he tested,
[18] I'm going to move to strike any testimony that he
[19] has about ingredients.

[20] MR. BHATIA: Look, you can do what you want,
[21] and if the Judge sustains it --

[22] MR. HOAG: I'm not finished talking. To the
[23] extent that he cannot answer questions as simple
[24] as what ingredients have you tested, I'm going to
[25] move to the strike any testimony he has at trial

[1] A I can give you some of the ones -- well,
[2] let's see.

[3] MR. BHATIA: Before you answer -- Joseph, is
[4] there any issue about trade secrecy here that we
[5] have to be concerned about because of the failure
[6] to enter into a protective order?

[7] MR. ARCHIE: John, my understanding is that
[8] the plaintiffs have not entered into a protective
[9] order here; is that correct?

[10] MR. HOAG: I don't know what your
[11] understanding is.

[12] MR. ARCHIE: What's your understanding of
[13] whether there's a protective order in this case
[14] to cover trade secrets?

[15] MR. HOAG: I don't know. I just know you
[16] got a fact witness, and I need to know what he's
[17] going to talk about. To the extent you're not
[18] going to let him talk about it, again, I'm going
[19] to move to strike it. It's up to you. It's your
[20] call.

[21] MR. BHATIA: Rick, if you believe that
[22] answering his question can be done so without
[23] implicating trade secrecy concerns, I think you
[24] should answer it and tell him the ingredients or
[25] design changes that you are familiar with while

[1] at the company that you can recall as you sit
[2] here today.

[3] THE WITNESS: Okay.

[4] MR. BHATIA: If something later refreshes
[5] your recollection and the Judge allows you to
[6] testify at trial, so be it.

[7] Q And to the extent that you are leaving
[8] things out, Rick, I want to know that you are leaving
[9] them out. If there's things you know that you are not
[10] going to tell me because you personally not being an
[11] attorney have interpreted to mean something you are
[12] not allowed to talk about, let me know.

[13] A Okay. I'll try to do some in generalities
[14] and some of it in specifics to give you an answer that
[15] you feel is responsive. The ingredients -- in
[16] categories, the ingredients that we would review would
[17] be any ingredients that are added to tobacco, which
[18] would be the types of ingredients that were on the
[19] list that as typically disclosed to the government and
[20] the US and was made public in 1994, those ingredients
[21] added to tobacco.

[22] Then in another category would be
[23] ingredients in any of the components of the cigarette.
[24] So they could be in the cigarette paper or the
[25] adhesives or the filter, and also ingredients make up

[1] evaluate all the items on the disclosure.

[2] I guess about the time I arrived, we were in
[3] the process of evaluating, as another example,
[4] evaluating guar gum.

[5] Q What was that?

[6] A Guar gum.

[7] Q How do you spell that?

[8] A G-U-A-R, gum. And as an ingredient for
[9] making tobacco sheet. So those are some examples, and
[10] those are the categories to try to better define them
[11] for you.

[12] Q Are those the only examples you can think
[13] of?

[14] A Let me think for a second. The ingredients,
[15] I guess, besides new ingredients -- and we are always
[16] trying to stay abreast of literature for new
[17] information on ingredients that we currently have in
[18] use, and so it might be that there might on occasion
[19] new literature might pop up on any of the ingredients
[20] we currently have that are being used.

[21] I can't say I can remember actively having
[22] to review any of them, but any of the ingredients that
[23] were on that list that was made public in 1994 that
[24] were our ingredients, we were always trying to make
[25] sure we are knowledgeable of all the current

[1] the packaging. In those areas, many times the things
[2] like paper, packaging would come from a vendor, and so
[3] that would require us to get disclosure from the
[4] vendor to detail out what the ingredients are that
[5] they use so we can evaluate them.

[6] And then, of course, since it was
[7] ingredients as well as cigarette designs, cigarette
[8] designs would include things such as considering the
[9] manufacturing of a different porosity of cigarette
[10] paper as an example, or as I said before, a design
[11] that is unique as the new electrically heated
[12] cigarette that we now have in consumer testing, and
[13] all of the ingredients in it as well as, you know, its
[14] design in total.

[15] A couple of specific ingredients, for
[16] example, that we have reviewed that I can recall,
[17] there was a compound a few years back -- I think it
[18] was the number on it KR2978.

[19] Q Say that again please.

[20] A CR2978, I believe that's correct. It was an
[21] ingredient we reviewed as a possible additive to
[22] tobacco. We have also tested various ingredients that
[23] were, for example, inks on packaging material, where
[24] the vendor would want to change a color or something,
[25] and they would provide us the disclosure, and we would

[1] literature.

[2] Q Which of those ingredients were
[3] characterized as your ingredients? Can you list
[4] those?

[5] A Well, that list from 1994 was 599 items
[6] long.

[7] Q Right.

[8] A And so I couldn't possibly sit in here and
[9] list the entire portion of that that was ours.

[10] Q Well, how many of them can you list that are
[11] yours, meaning Philip Morris'?

[12] A I can give you some examples.

[13] Q I would like you to list as many as you know
[14] of right now?

[15] A Well, we have various sugars. There could
[16] be five or six sugars, fructose, sucrose, like that.
[17] We have cocoa, chocolate, propylene glycol.

[18] Q How do you spell that?

[19] A P-R-O-P-Y-L-E-N-E, glycol, G-L-Y-C-O-L;
[20] glycerin; licorice, if I haven't said it already; guar
[21] gum I mentioned already that we evaluated.

[22] Probably -- part of my problem is as I go, the further
[23] I go down the list, I'm not sure whether they are ones
[24] that were on that list from that year, whether they
[25] were on any list that belonged to Philip Morris,

[1] whether I might be listing something that may have
[2] been on somebody else's list and not my list. I'm
[3] concerned about making those errors.

[4] But the common ingredients other than those
[5] may be raisin juice, honey, prune juice. Let's see,
[6] what else? I'm terrible about doing this kind of
[7] recall.

[8] MR. BHATIA: That's okay. The jury will
[9] understand that.

[10] A Probably citric acid, ammonium hydroxide,

[11] Q Ammonium hydroxide?

[12] A Yes.

[13] Q Is that different than ammonia?

[14] A Yes, it is.

[15] Q In what way is it different?

[16] A Well, it's got a hydroxyl group.

[17] Q What does that mean?

[18] MR. BHATIA: It's got the OH.

[19] A Yes, and oxygen and a hydrogen.

[20] Q In what way does that make it different than
[21] ammonia?

[22] A Ammonia is a nitrogen and three hydrogens.
[23] This has got an additional oxygen and hydrogen.

[24] Q Now, is ammonia among the additives that you
[25] evaluated or that you are aware of?

[1] acceptability?

[2] A When somebody says they are considering
[3] using an ingredient, they will let us know, and we
[4] would ask for detailed information so we know exactly
[5] what we are talking about, what exactly the ingredient
[6] is. And we would evaluate the scientific literature
[7] to find out anything we can about the compound. We
[8] would evaluate the appropriate regulations to
[9] determine its regulatory status. And then we would do
[10] appropriate tests, depending on where the ingredient
[11] was intended to be used and at what level.

[12] If it was an ingredient added to tobacco, it
[13] would probably be pyrolyzed so we got an idea of what
[14] it might pyrolyze into. There are a battery of tests
[15] that are considered, and some of them might include
[16] you put it on a cigarette and burn the cigarette and
[17] evaluate the smoke chemistry and do some biological
[18] assays.

[19] Q So is that what you do when there's a new
[20] ingredient, possible new ingredient? Do you do all
[21] those things?

[22] A We do whatever is appropriate. Some
[23] ingredients may have a very, very low use level. For
[24] example, if it was in packaging, it's not really
[25] necessary to wonder what it burns into, because it's

[1] A Ammonia, no. Ammonium hydroxide, yes, is on
[2] the list.

[3] Q What, regular ammonia?

[4] A No.

[5] Q Do you know ammonia, whether or not it's in
[6] cigarettes?

[7] A In cigarettes like in tobacco?

[8] Q In tobacco.

[9] A I'm not sure, but I believe that ammonia may
[10] be natural to tobacco. It is in cigarette smoke.

[11] Q So you do not know whether ammonia is added
[12] to tobacco or not; is that correct?

[13] A No. I know that ammonia is not on our
[14] ingredients list. I know ammonium hydroxide is or
[15] was. There are ammonia like compounds. There is no
[16] ammonia.

[17] Q What is the purpose of ammonium hydroxide to
[18] the cigarette; what does that do?

[19] A Here the -- it's a little bit outside of my
[20] area of expertise. I'm not a product developer. I'm
[21] not a flavorist. I review these ingredients for their
[22] acceptability to be used in the product, but I don't
[23] develop them or pretend to be a flavorist or a product
[24] developer.

[25] Q How do you go about reviewing them for their

[1] not going to be burned. It's on the packaging
[2] material.

[3] On the other hand, if it's an ingredient, as
[4] I said, added to tobacco, yes, it would have to go
[5] through much more extensive evaluation such as I've
[6] described.

[7] Q So if it's an ingredient that's added to
[8] tobacco, and then you (Inaudible.) --

[9] A You broke up. Can you repeat the question.

[10] Q If it's an ingredient in the cigarette that
[11] is proposed to be in the cigarette, do you put it in a
[12] regular cigarette and then do biological assays?

[13] A For a new ingredient that came to us now, we
[14] would do the literature reviews and regulatory
[15] reviews -- and you may find from all of that that you
[16] have got enough information, that you may not have to
[17] generate any testing data, because it's all already
[18] known. But where you are lacking information, and
[19] particularly where the use levels are higher than
[20] something that might be at very, very low use levels
[21] and you don't have the information already in the
[22] literature, then you would have to do these tests.

[23] Q You've heard of the term synergy, right?

[24] A Yes.

[25] Q What does it mean to you?

[1] A To me synergy means you take, for example,
[2] two different items, and when you put them together,
[3] the effect that you get, whatever effect it is that
[4] you are measuring, is much greater than you would
[5] expect if you just added the effects of the two
[6] individual items separately.

[7] Q So every proposed new ingredient tests for
[8] the possible synergistic effect the ingredient will
[9] have with all the other ingredient that are already in
[10] cigarettes? For any proposed new ingredient, you do
[11] tests of the ingredient. If it's going to be in the
[12] tobacco itself, do you do tests of the ingredient to
[13] see whether or not it has any synergistic effect with
[14] any of the other ingredients that are already in the
[15] cigarette?

[16] A No. We do have some data to address that
[17] concept, but our testing guidelines and approaches are
[18] based on models from what is done in the food
[19] industry. And there they also do not test for synergy
[20] of various ingredients. The ingredients are tested
[21] alone, evaluated, determined to be acceptable for
[22] their use, and we model that approach.

[23] Q What products in the food industry are set
[24] on fire and intentionally inhaled into the lungs 20 or
[25] more times a day for years by an average consumer?

[1] (Court reporter reads question.)

[2]
[3] Q You would have the test each of these
[4] ingredients for the possible effect it would have on
[5] all of the other additives and carcinogenic components
[6] in cigarette smoke, correct?

[7] MR. BHATIA: You have my objection, right?

[8] Objection to the form.

[9] A No. As I said before, we model our testing
[10] approach after the kinds of concepts that are applied
[11] in the food industry. And evaluating an ingredient
[12] before it's approved for every possible other
[13] ingredient it might be used with is simply not done in
[14] those industries. And a lot of very good experts, I
[15] think, have had input into developing that system. So
[16] I think there's a lot of precedent to suggest that
[17] that's not a piece of doing an appropriate review.

[18] Q Well, to do the best possible science,
[19] that's what you would do, isn't it, you would actually
[20] test the synergistic effect that the new ingredient
[21] has on all the other additives and components of
[22] cigarettes, correct?

[23] MR. BHATIA: Object to the form of the
[24] question.

[25] A To do the best possible science, and then

[1] A Well, clearly the answer to your question is
[2] none. Since we are talking about synergy, I'm
[3] assuming that you're concerned about whether that
[4] concept applies to synergy with cigarettes. I think a
[5] parallel might be you take ingredients that are put in
[6] a food and then either manufacture it, such as the
[7] bread that you are buying before it's baked by the
[8] manufacturer, or you put the ingredients in and then
[9] you bake it, or you're going to you take various
[10] ingredients and cook at home.

[11] Yes, you are right. They are not smoked.
[12] They are not inhaled. But smoke when you are cooking,
[13] you are inhaling some of the things that come out of
[14] the pan, so there is that. But they are intended to
[15] be ingested, but nonetheless, they are combined and
[16] heated at times for items that are cooked. So I think
[17] there are a lot of similarities.

[18] Q But you would admit to do this in a
[19] scientific manner that really takes into consideration
[20] the safety of the public, you would have to test each
[21] of these ingredients --

[22] MR. BHATIA: Objection to the form.

[23] A Could you just repeat it one more time,
[24] please.

[25]

[1] could you continue from there.

[2] Q You would test for the synergistic effect in
[3] new ingredients on all the other additives contained
[4] in the cigarettes, including all the carcinogenic
[5] components in tobacco, correct?

[6] MR. BHATIA: Object to the form.

[7] A I think the answer is the same one that I
[8] already gave you, that to me, you know, one way to be
[9] clear that a thorough review is being done is to use
[10] an approach that is modeled after what's done for
[11] additives in the food industry. So we take an
[12] approach that reviews our additives similar to that
[13] done for foods. When a food additive is approved by
[14] the FDA or grasped by the FDA or another organization,
[15] those reviews look at the item and its intended use,
[16] but do not do reviews of call the possible
[17] interactions. So that when you get an approval of
[18] something and they say you can now use vanilla -- oh,
[19] vanillin is another one you can add to the list of
[20] ingredients that we have on that list -- you can now
[21] use vanilla in foods. But they don't say on bottle of
[22] vanilla you can use this with lemon and with chocolate
[23] but don't use it with coconut because we never tested
[24] it.

[25] Q Do you consider a cigarette to be a food?

[1] A No.

[2] Q But the truth is cigarettes are a drug,

[3] correct?

[4] A No.

[5] Q Well, hypothetically assuming that

[6] cigarettes are a drug, what type of testing procedure

[7] would you do differently than the testing procedure --

[8] MR. BHATIA: What?

[9] MR. HOAG: Pardon me?

[10] MR. BHATIA: I said what?

[11] MR. HOAG: Who said what, the witness or the

[12] attorney?

[13] MR. BHATIA: Objection to the form.

[14] MR. HOAG: Would you please answer the

[15] question. I apologize for the attorney saying

[16] what. It has nothing to do with the question.

[17] MR. BHATIA: You're breaking up on the

[18] speaker. It's not my fault.

[19] A The -- I'm sorry. I forgot what the

[20] question was.

[21] MR. BHATIA: The speaker keeps cutting out.

[22] We can't hear you. The reporter is also having

[23] difficulty.

[24] MR. HOAG: I understand telephone

[25] depositions are difficult than face-to-face

[1] determined to be regulated as a drug, then the

[2] government regulating them -- and we could assume I

[3] suppose that it would be the FDA -- would have to

[4] determine what testing requirements would be

[5] appropriate.

[6] Q Well, do you know what testing requirements

[7] are appropriate for drugs as opposed to food?

[8] A It depends on the drug. It varies very much

[9] from drug to drug, depending on what they are intended

[10] to be used for and how long they are to be used

[11] and whatnot. I think there's a considerable

[12] difference from drug to drug in the type of data

[13] that's required.

[14] Q Well, let's assume that the drug is a drug

[15] that is inhaled every day by the consumers of the

[16] substance, and it's inhaled on the average of, what,

[17] more than 20 times a day by the consumer the

[18] substance. And the substance is known to be

[19] carcinogenic, and the substance is known to cause

[20] hundreds of thousands of death each year. Under those

[21] circumstances in my hypothetical, what type of

[22] requirements would there be for that particular drug

[23] as far as testing new ingredients?

[24] MR. BHATIA: Objection to the form.

[25] A I apologize for being difficult, but there

[1] depositions. If the court reporter cannot hear

[2] me, if the court reporter can just tell me at the

[3] time that occurs -- I know that's difficult,

[4] because you have to wait until I'm finished

[5] before you can tell me you can't hear me, but let

[6] me know that.

[7] Were you unable to get my last question?

[8] THE COURT REPORTER: Yes. Would you repeat

[9] it.

[10] Q Hypothetically, if cigarettes are a drug,

[11] what testing procedures should you follow that are

[12] different than testing procedures you would use

[13] assuming cigarettes are a food?

[14] MR. BHATIA: Objection to the form.

[15] A I have to say that for starters, we have

[16] been talking about the testing we do, and remind you

[17] that what we review is new and proposed additives and

[18] changes to the cigarette design, and you are asking me

[19] about testing cigarettes. I'm telling you that what

[20] we are talking about is testing additives and design

[21] changes. So we have modeled our testing after the

[22] food industry.

[23] Now, to try to respond to your hypothetical

[24] about cigarettes being a drug, I think the only thing

[25] I could say would be that if cigarettes were

[1] are pieces here that seem to disagree in the parts of

[2] the question. On the one hand you describe all these

[3] characteristics of the drug, and then at the end you

[4] said so in that drug how would I go about testing a

[5] new ingredient. And I think my answer there is that

[6] okay, now we focus on the ingredient and we do the

[7] ingredient review as is appropriate for any ingredient

[8] review.

[9] And part of the ingredient review that might

[10] apply, based on your description, is the fact that

[11] this ingredient is going to be inhaled and it's going

[12] to be inhaled daily. And so you would want to do

[13] testing that, you know, is at least some of your

[14] testing by inhalation, and probably do some

[15] preliminary screening types of studies which are

[16] fairly standard, and of course start, as I mentioned

[17] much earlier in another question, with

[18] characterization of the ingredient, you know, what is

[19] it exactly, in looking at the literature and see

[20] what's known and evaluate its regulatory status and

[21] all that.

[22] Q In your opinion if the substance was the one

[23] I described, one that was ingested more than 20 times

[24] a day by consumers and that resulted in the deaths

[25] hundreds of thousands of people each year, would you,

[1] *in your opinion, need to evaluate the synergistic*
 [2] *effect of each possible new ingredients for that drug?*

[3] MR. BHATIA: Object to the form.

[4] A Again, your question was about do you need
 [5] to evaluate the synergy, and I would have to repeat my
 [6] comments before about synergy, because -- and your
 [7] details and your characteristics of the product really
 [8] don't bear on the issue of synergy to me. It's a
 [9] matter of we have well-established processes for
 [10] reviewing food ingredients, and some established for
 [11] evaluating drugs and ingredients in various drugs.

[12] Our synergistic interactions tested so that,
 [13] for example, when a new drug is approved, a person
 [14] might take it with any of 30 or 40 other drugs that
 [15] are on the market, are they required to test their new
 [16] drug simultaneously with the other drugs that might be
 [17] used with, no, that's not required.

[18] Q But that wasn't my question at all.

[19] A Oh, I'm sorry.

[20] Q If you have to assume the drug itself is
 [21] being changed, the drug itself, the new ingredients,
 [22] how it's -- to what synergistic effect is or is not
 [23] with all the old ingredient drug, that's what I'm
 [24] talking about. When I asked the question about
 [25] synergy, it was not comparing the drug and how it

[1] talking here about cigarettes, and I believe that's
 [2] what your question is really about, and my
 [3] responsibility is to evaluate the ingredients, then I
 [4] can tell you that the same thing that I told you
 [5] before, and that is when we have a new ingredient,
 [6] flavor, or whatever, that we review it, going through
 [7] the literature, going through its regulatory status
 [8] doing whatever testing we think is appropriate to make
 [9] sure its acceptable. And we model that review after
 [10] the kind of testing that's required for flavors in the
 [11] food industry. And since that's the way I do it, then
 [12] clearly my opinion is that's an appropriate way to
 [13] evaluate. And as I told you before, the food industry
 [14] does not require all these evaluations of its synergy
 [15] with other ingredients that it may be used with.

[16] For example, if somebody wants to sell a new
 [17] cookie, and they are going to put five different
 [18] ingredients in as flavors, they are not required
 [19] before they sell this cookie to test those five
 [20] ingredients together. They know that each one of them
 [21] is approved for use in cookies, and they can use them.
 [22] So that's the way we do it, and that's what I think is
 [23] appropriate.

[24] Q So you believe it's appropriate to analogize
 [25] a cigarette to a cookie; is that correct?

[1] reacts with the other drugs, totally different drugs.
 [2] It was comparing the ingredient to the old drug. If
 [3] you are going to add a new ingredient to a drug, it
 [4] means you are adding something different that wasn't
 [5] in the drug before.

[6] What I'm saying is in your opinion is it
 [7] necessary if the drug as I have described, when
 [8] inhaled, results in deaths of hundreds of thousands of
 [9] times a year for those who inhale it long enough,
 [10] that's a fact, then if you had add a new ingredient to
 [11] that drug, in your opinion is it necessary to test the
 [12] synergistic effect that that new ingredient has with
 [13] the other ingredients in the cigarette, especially
 [14] those ingredients that are known to cause cancer?

[15] MR. BHATIA: Objection to the form of the
 [16] question.

[17] A On the one hand, because I think it's best
 [18] to try to answer your question in two parts. In the
 [19] world of drug reviews, when an ingredient is changed
 [20] for a drug that's on the marketplace and which of the
 [21] ingredients, whether it's a flavor or whether it's an
 [22] active ingredients, I have to say that I don't know
 [23] enough detail to know what would be required in the
 [24] current regulatory environment in the US for drugs.

[25] On the other hand, since we are largely

[1] A No, no, no, no. I was trying to make an
 [2] example for you about this idea of synergy, and I
 [3] thought it might be a good way to explain it. I'm not
 [4] comparing in toto cigarettes to cookies.

[5]

[6] (Break taken.)

[7]

[8] Q Did you bring any documents with you today?

[9] A Is that to me?

[10] Q The witness.

[11] A No, I didn't.

[12] Q Have you reviewed any documents in
 [13] preparation for your testimony?

[14] A Let's see. I looked over my CV a few
 [15] minutes ago. I don't think so, no. No, I didn't.

[16] Q Have you prepared any reports in preparation
 [17] for your testimony?

[18] A No, I did not.

[19] Q Now, your CV, I've just had a chance to
 [20] briefly review it. You were the Chief of the
 [21] Pharmacology Division for the US Army Medical
 [22] Institute of Chemical Defense from 1989 to 1993,
 [23] correct?

[24] A Yes.

[25] Q And among your duties were to plan and

[1] organize basic and applied drug development research;
[2] is that correct?

[3] A Yes.

[4] Q Is drug development research different than
[5] food development research?

[6] A I've never done food development research,
[7] so I couldn't compare the two.

[8] Q Have you done any product research for
[9] Philip Morris?

[10] A I'm sorry after you said product, the
[11] speaker went dead for about a second.

[12] Q Have you done any product development
[13] research since you have been employed at Philip
[14] Morris?

[15] A No. The work that I've described to you as
[16] far as evaluating product changes and new ingredients
[17] is in support of it, but I'm not a product development
[18] person.

[19] Q So what you do supports new product
[20] development for Philip Morris; is that correct?

[21] A Yes.

[22] Q And in what way does it support new product
[23] development?

[24] A Simply, you know, simply in that the
[25] responsibility to look at these new, you know, any new

[1] preclinical, and so the final development efforts of
[2] it would be handed off to an organization in
[3] Frederick, Maryland. They had most of the interface
[4] with the FDA, and they would deal with issues like
[5] that. I was more familiar with our evaluations which
[6] had to do more with the active ingredient than with
[7] the formulation. So I don't have the experience to
[8] answer that for you.

[9] Q So do you know whether or not if you are
[10] testing a drug and you add a new ingredient to the
[11] drug, do you know whether or not you are required to
[12] test for the synergistic effect of that new ingredient
[13] on all the other ingredients in the drug?

[14] A From my knowledge of it, which again as I
[15] said is a little bit indirect, it's not really a
[16] matter of whether you test for the synergy with the
[17] other ingredients in the drug. That's not done. It's
[18] a matter of does the change in that would partly be
[19] determined by is there something like just a flavor or
[20] is it the active ingredient itself. Would it be
[21] considered enough of a reformulation that that new
[22] formulation would need some testing, but not
[23] specifically to pursue synergies between some
[24] ingredient you changed and others.

[25] Q But you may pursue that, correct?

[1] ingredient, you can consider if it's used, a new
[2] product. And any product change, if it's used, can be
[3] considered a new product. And so our evaluations of
[4] those efforts are work in support of what's going on
[5] in product development.

[6] Q You were in the military as a Chief of the
[7] Pharmacology Division. It says in your resume that
[8] among other things your duties included preclinical
[9] pharmacology and clinical toxicology of new
[10] pharmaceuticals. What does that mean?

[11] A That means that evaluations of candidate
[12] pharmaceuticals would require certain reviews in two
[13] categories, because to get a new product approved, the
[14] FDA basically requires for drugs proof of safety and
[15] proof of efficacy. So efficacy for a drug in the
[16] early stages requires preclinical pharmacology, and
[17] safety would require the non-clinical toxicology.

[18] So that's basically the testing and the
[19] pre-clinical or non-clinical really talks about work
[20] that's done outside of clinic research.

[21] Q Now, if you add a new ingredient to a drug
[22] that already exists, has it becomes a new drug or is
[23] it still the same drug?

[24] A Well, remember my testing there -- this was
[25] a research facility, and this testing was, you know,

[1] A No. You would possibly, and to some extent
[2] need to pursue evaluation of a new formulation. If
[3] it's a major change, for example, if it's a change to
[4] a new active ingredient, it's a new drug, and you are
[5] going to do everything all over again. If it's simply
[6] a flavor change, it may not require hardly if any
[7] testing, although as I said, I don't know the details
[8] not having been firsthand involved. But you would
[9] just need to or not need to look at the whole
[10] formulation, but not specifically say okay, these are
[11] the 15 things we have in this formulation, now we have
[12] to do tests of their synergies of these 15 items. No,
[13] that's not the way it's done.

[14] Q How does one go about ascertaining if
[15] something is a new active ingredient?

[16] MR. BHATIA: Object to the form.

[17] A Our work was basic research, and when you
[18] look at candidate chemicals each one was a different
[19] chemical entity. And if they became viable drugs,
[20] they would be the active ingredient in the drug. One
[21] would be different than another. They are different
[22] chemical structures.

[23] Q The additives that are in cigarettes may
[24] include chemical ingredients, right?

[25] A Yes, most anything is chemical.

[1] Q So in order to know whether or not those are
[2] active ingredients that require extensive testing, the
[3] only way you can really know that is you have to test
[4] them on the actual product, correct?

[5] MR. BHATIA: Object to the form.

[6] A No. I think we are stumbling over
[7] terminology. In drug development, the term active
[8] ingredient means specifically the chemical that is in
[9] there to have the effect the drug is supposed to have.
[10] So if you are talking about an aspirin, the active
[11] ingredient is acetylsalicylic acid.

[12] Q Are there any drugs other than cigarettes
[13] that are legally sold that result in the death of
[14] thousands of people each year?

[15] MR. BHATIA: Object to the form.

[16] A I have a problem with your saying drugs
[17] other than cigarettes which implies that drugs are
[18] cigarettes or cigarettes are drugs, excuse me, and
[19] they are not.

[20] Q Well, assuming cigarette are drugs, in this
[21] hypothetical, assuming cigarettes are drugs, are there
[22] any other drugs legally on the market that result in
[23] the death of hundreds of thousands of people each
[24] year?

[25] MR. BHATIA: Object to the form.

[1] Q And if those hypotheticals, assuming those
[2] hypotheticals are true -- I know you don't assume
[3] that -- but assuming they are true for purposes of
[4] this question -- the testing procedures for new any
[5] new ingredient for that product would have to be more
[6] stringent than any other drug product, legal drug
[7] product, correct? Assuming hypothetically that
[8] cigarettes are a drug, a legal product that's a drug
[9] that causes the death of hundreds of thousands of
[10] Americans each year, assuming that hypothetically if
[11] that is right, would it then be necessary to test any
[12] new ingredient added to that particular drug in a more
[13] stringent manner than tests for any other legal drug
[14] in the United States, correct?

[15] MR. BHATIA: Object to the form of the
[16] question.

[17] A To your question regarding the testing of
[18] the ingredients of cigarettes, my answer would be no,
[19] that is not correct. The kinds of things that you
[20] consider when you are testing an ingredient such as a
[21] flavor are how is it going to be used, what level is
[22] it going to be used at. Those are the kinds of
[23] factors that determine what type of testing you need
[24] to do.

[25] So if you are going to use it in a food and

[1] A I don't know the entire US listing, assuming
[2] you are talking about just the United States, of drugs
[3] that are available, so I can't tell you for sure. But
[4] if you are asking are there drugs that are sold that
[5] kill 400,000 people a year in the United States, I
[6] don't believe that would be the case.

[7] Q So to the extent hypothetically that
[8] cigarettes are a drug that do kill hundreds of
[9] thousands of people in the United States each year,
[10] cigarettes to that extent, if they are a drug, would
[11] be a unique drug, correct?

[12] MR. BHATIA: Object to the form.

[13] A That was very hard to follow. Could you
[14] repeat it, please.

[15] Q Well, hypothetically if cigarettes are a
[16] drug, and if hypothetically cigarettes do result in
[17] the death of hundreds of thousands of Americans each
[18] year, cigarettes would, in fact, be a unique drug; is
[19] that correct?

[20] MR. BHATIA: Same objection. Object to the
[21] form.

[22] A It would seem so with those hypotheticals.
[23] but again, as I said, in your preceding question, I
[24] wasn't totally knowledgeable of everything that's
[25] available.

[1] it's going to be used at one part per million, then
[2] you would test it at a fairly low level and for very
[3] limited testing. On the other hand, if it's going to
[4] be used in a cigarette as opposed to a food, you would
[5] not be so much concerned about tests that were
[6] designed by ingestion, although those would be very
[7] useful data, but you would want to have data if you
[8] were designing tests that address the inhalation.

[9] Q Are you talking about that addressing the
[10] inhalation of the ingredient standing alone?

[11] A It depends, again, on the ingredient. As I
[12] told you, when we evaluate ingredients, we start by
[13] searching the literature, knowing exactly what the
[14] ingredients are, and the regulatory status. From that
[15] you learn a lot. And the kind of thing you could
[16] learn that addresses your question might be is this an
[17] ingredient that has such a low vapor pressure that it
[18] will be, if used in a cigarette, it will be in the
[19] smoke exactly as that ingredient, in which case that
[20] is the fact, what is in the smoke.

[21] On the other if it does not have a low vapor
[22] pressure, it might pyrolyze into other compounds, and
[23] so when you use it in a cigarette, it would not be so
[24] much the starting ingredients that you would have.
[25] Nonetheless, if you put it on a cigarette and you test

[1] the smoke, whichever form it takes, you are testing
[2] its use in the cigarette as intended.

[3] Q Now, are you saying those that don't have
[4] low vapor pressure, all of those new ingredients are
[5] tested are added to a regular cigarette and then
[6] tested with inhalation studies?

[7] A No. I was giving you an example of one of
[8] the kinds of details that you would have to consider
[9] in making sure that you are doing appropriate testing.

[10] Q Well, how often are inhalation studies done
[11] on these new ingredients that don't have low vapor
[12] pressure that involve inhalation study of adding that
[13] new ingredient to a regular cigarette?

[14] A Well, part of that is a function of how many
[15] new ingredients are being reviewed. But many, almost
[16] all of the high use items, the ones that don't have a
[17] low vapor pressure have inhalation studies done on
[18] them.

[19] Q The inhalation studies that are done -- let
[20] me back up. You said ones that don't have low vapor
[21] pressures, those do have inhalation studies done?

[22] A Yeah. That's the ones you are asking about,
[23] the ones that don't have low vapor pressure.

[24] Q You said almost all of those do?

[25] A That's right.

[1] marketplace in tar delivery.

[2] Q But the Reference cigarette has almost all
[3] of the additives removed from it, doesn't it?

[4] A Yes. That's a very important feature of it,
[5] because that allows you to clearly be able to tell the
[6] difference between the Reference cigarette without
[7] your test additive and with your test additive. If
[8] you had a lot of additives in the cigarette already,
[9] it would be more difficult to see what if any additive
[10] that you are testing is contributing.

[11] Q But that totally fails the test to any
[12] possible synergistic effect with all the other
[13] additives in cigarettes, correct?

[14] A It intentionally makes it possible to
[15] evaluate that ingredient and see what if anything that
[16] ingredient does to cigarette smoke, because with
[17] anything else in there, it just complicates the study
[18] so that you could not determine whether that
[19] ingredient is acceptable or not.

[20] And yes, that's correct, it therefore does
[21] not look at synergies. And as I mentioned to you
[22] before, that is exactly the kind of approach that is
[23] taken with food additives, where if you are testing a
[24] food administrative, you put it in the animal's food,
[25] and the laboratory rats would be eating it, but they

[1] Q How do you decide which ones don't?

[2] A As I said, it's a function of knowing what's
[3] in the literature, and what's known about the
[4] compound, and sometimes preliminary testing to further
[5] characterize the identity of the compound on how it
[6] performs when it's pyrolyzed. And if you are lacking
[7] information, you would need to go on to advanced
[8] testing. If they used at low levels, they would need
[9] less testing than if they used at high levels. That
[10] would be the case, as I said, in the food industry as
[11] well.

[12] Q Those that have inhalation studies done,
[13] exactly how is that accomplished?

[14] A Well, basically a typical inhalation
[15] exposure, the ingredient is put on a cigarette. The
[16] test cigarettes are smoked according to standardized
[17] FTC conditions, and the smoke atmosphere is exposed to
[18] laboratory rats.

[19] Q So you said the ingredient is put on test
[20] cigarettes?

[21] A Yes.

[22] Q What is a test cigarette?

[23] A Well, the most common one used these days is
[24] a University of Kentucky Reference cigarette called a
[25] 1R4F, which represents about the middle of the US

[1] would be in their basic food with limited additives,
[2] as limited as possible, with only that one test
[3] additive being included.

[4] Q So actually, to your knowledge, Philip
[5] Morris never actually tests the synergistic
[6] interaction that may occur with the additives that are
[7] already in cigarettes and the new ingredient, correct?

[8] A No. That is not correct. We have some data
[9] that has numerous ingredients in it. But I think the
[10] key point on the typical testing is that if you want
[11] information about a given ingredient as to whether
[12] it's acceptable or not, you have to test it alone.

[13] Q So the vast majority of the tests on new
[14] ingredients are just testing the new ingredient by
[15] adding it to a Reference cigarette that has most of
[16] the additives removed, correct?

[17] A That is correct.

[18] Q What percentage of the time do you actually
[19] do tests on the new ingredient using a cigarette with
[20] all the additives that are actually in commercial
[21] cigarettes?

[22] A Almost never. As I said, we have some data
[23] with combinations of ingredients, but the routine
[24] large majority of the time, we are trying to do a
[25] thorough review of an individual ingredient as to its

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[1] acceptability. Having other ingredients in the test
[2] cigarette would just complicate our ability to
[3] evaluate it.

[4] Q Well, it would be possible to do that,
[5] because you do it sometimes, correct?

[6] A It's possible to put more than one -- of
[7] course it's possible to put more than one ingredient
[8] on a cigarette, but it serves no purpose.

[9] Q Well, wouldn't the purpose be to find out if
[10] there's a synergistic effect between some of those
[11] additives and the new ingredient that you are putting
[12] in there?

[13] A Yes, if you wanted to put more than one item
[14] on a cigarette, you could do it for the purpose of
[15] seeing if there's synergistic effect. But as I had
[16] said before, we try to do a responsible job of
[17] evaluating our ingredients, and therefore we model our
[18] testing after well-established approaches that are
[19] used in the food industry. And looking at synergy is
[20] not the approach, it's doing a thorough review of the
[21] individual ingredients.

[22] Q And Philip Morris chooses to test this
[23] product as if it's a food, even though the company
[24] knows this product is a drug, correct?

[25] MR. BHATIA: Object to the form.

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[1] Q Have you ever reviewed any Philip Morris
[2] documents that describe cigarette as drugs?

[3] A No, I haven't, other than having seen
[4] excerpts of them in newspaper clippings.

[5] Q You have seen excerpts of Philip Morris
[6] documents that stated cigarettes are drugs?

[7] A Either periodically on the news or in the
[8] newspaper, whatever. But I have never looked at
[9] documents firsthand regarding that.

[10] Q Do you have any interest in doing that?

[11] A No.

[12] Q Has defense counsel provided you with any
[13] such documents to review?

[14] A No.

[15] Q Has defense counsel provided you with any
[16] documents to review?

[17] A No, sir.

[18] Q Now, on the issue of new product design --
[19] before we get to that, are there other ingredients
[20] that haven't already named that you know of that are
[21] in cigarettes?

[22] A When I was talking before I mentioned
[23] vanillin, I told you that was one I had mentioned
[24] before that you could add to the list.

[25] Q How do you spell that?

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[1] A Philip Morris does not test its product as a
[2] food. We use the food industries, and government
[3] regulatory established approaches for the food
[4] industry as a model on which we base our testing
[5] approaches.

[6] Q You don't test the cigarette protect as if
[7] it were a drug, correct?

[8] A That's correct. We test it as if it's a
[9] cigarette.

[10] Q Does Philip Morris consider cigarettes to be
[11] a drug?

[12] A No.

[13] Q What do you base that on?

[14] A I guess very simply the fact that they are
[15] regulated under many government organizations and they
[16] are not regulated under drugs, as one piece of
[17] information. And secondly, they are, in my mind --
[18] and you asked about Philip Morris, I'm speaking for
[19] myself -- they are sold for people to smoke for the
[20] sole purpose of enjoying the smoking. Drugs are sold
[21] to treat diseases.

[22] Q Have you ever reviewed any Philip Morris
[23] internal documents that refer to cigarettes as drug
[24] delivery devices?

[25] A No, I haven't.

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[1] A V-A-N-I-L-L-I-N.

[2] Q Any others?

[3] A If I think of any as we go, I'll be sure to
[4] point them out to you.

[5] Q Right now you have exhausted your memory as
[6] to the ingredients of cigarettes; is that correct?

[7] A I'm take a few seconds here to think and try
[8] to remember what I've said here already. Where we
[9] ended on that list, I guess, was ammonium hydroxide,
[10] and diammonium phosphate would be another one. Not at
[11] the moment.

[12] Q How many carcinogenic components are in a
[13] cigarette?

[14] A In cigarettes?

[15] Q And when I say cigarettes, I'm including the
[16] smoke that emanates from a burning cigarette.

[17] A Oh, okay. I'm not that familiar with
[18] analysis of cigarettes excluding the smoke, but I have
[19] seen literature, publications that or various
[20] publications that probably list -- and depends on what
[21] you define as a carcinogen, but these literature
[22] references with their definitions might come up with
[23] something like fortyish compounds.

[24] Q And how many of those can you name?

[25] A I don't know, maybe 10 or 20 off the top of

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- [1] my head.
- [2] Q What are the 10 or 20 you can name? Name
- [3] them now please.
- [4] A Benzene, formaldehyde, benzo(a)pyrene
- [5] dibenz(a)anthracene.
- [6] Q How do you spell that?
- [7] A D-I-B-E-N-Z-(A)-A-N-T-H-R-A-C-E-N-E.
- [8] Q Okay.
- [9] A So, let's see, where did I --
- [10] Q Is there whispering there? Is there
- [11] something you want to say?
- [12] MR. BHATIA: Are you sure it's not the
- [13] crackle of phone line? Man, you are one paranoid
- [14] guy.
- [15] A Nitrosamine or nicotine, NNK.
- [16] Q That's nitrosamine, correct?
- [17] A Yes, it is. Vinyl chloride. Let me list it
- [18] by category. Polyaromatic hydrocarbons, and there
- [19] could be about ten in it, but some agencies consider
- [20] some of them carcinogens and others not. So if I
- [21] start listing them, I'm not sure which ones I'll get
- [22] that are and which ones I'll get there aren't, so it's
- [23] easier for me to say poly-aromatic hydrocarbons. One
- [24] that I did already mention in that category was
- [25] benzo(a)pyrene, and dibenz(a)anthracene was another

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- [1] effect been tested by Philip Morris?
- [2] MR. BHATIA: Objection to the form.
- [3] A Could you repeat it, because the first part
- [4] of that I didn't catch.
- [5] Q I will repeat or rephrase it. Has the
- [6] synergistic effect of all those carcinogenic
- [7] components that you've named and those that you
- [8] haven't named ever to your knowledge been tested by
- [9] Philip Morris?
- [10] MR. BHATIA: Object to the form.
- [11] A We talked before about when we do
- [12] evaluations of cigarette design changes or new
- [13] ingredients, that often we do animal inhalation
- [14] studies, but we evaluate the smoke not only with
- [15] animal inhalation studies, but the smoke chemistry
- [16] analysis and some other studies. Therefore, in any of
- [17] those cases, we are looking at the smoke as a whole
- [18] with all of its composition.
- [19] Q Does that mean you don't test the
- [20] synergistic effect of one substance with another; is
- [21] that what you are saying?
- [22] A I think I know what you're asking. If do we
- [23] take, for example, benzene and vinyl chloride and
- [24] generate those as aerosols, not in smoke, not in
- [25] cigarettes, and see how they interact, no, we don't.

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- [1] polyaromatic hydrocarbon; 4-aminobiphenyl.
- [2] Q How do you spell that?
- [3] A 4-A-M-I-N-O-B-I-P-H-E-N-L-Y; 2-nitropropane;
- [4] 2-naphthylamine.
- [5] Q How do you spell that?
- [6] A 2-N-A-P -- I think it's
- [7] P-H-T-H-Y-L-A-M-I-N-E. I think hydrogen is listed by
- [8] some agencies as a possibility, although I'm not sure
- [9] it really is in smoke. I could sit and think a little
- [10] bit longer, but right now, that's what comes to my
- [11] mind.
- [12] Q You named about 11 substances of what you
- [13] recollect to be about 40 substances that are
- [14] carcinogenic in tobacco smoke, correct?
- [15] A No. Remember I told you that polyaromatic
- [16] hydrocarbons were a category, and there are probably
- [17] about ten in that.
- [18] Q But you only named about three or four.
- [19] A Yeah. But in the category there are about
- [20] ten, so -- I would say this list accounts for about 20
- [21] of them. Although you are right, specifically I
- [22] didn't specifically most of those.
- [23] Q Does do those substances, all those you have
- [24] named and the others you haven't named as carcinogenic
- [25] components of tobacco smoke, has their synergistic

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- [1] But as I told you, my responsibility is to look at
- [2] ingredients in cigarette design changes, and these are
- [3] not ingredients.
- [4] Q What is the difference between an ingredient
- [5] and all those things that you just listed that are
- [6] carcinogenic components of tobacco smoke?
- [7] A Ingredients are items that are added to the
- [8] product in its manufacture so that if you take a
- [9] cigarette and hold it in your hand, and everything
- [10] that's in there is an ingredient of that cigarette.
- [11] Q For example, when you have a new ingredient
- [12] to test, do you take that new ingredient and test it
- [13] on, for example, benzene, to see how it interacts with
- [14] benzene?
- [15] MR. BHATIA: Object to the form.
- [16] A If I understand your question, you are
- [17] looking for synergy interactions, and since the
- [18] ingredient, since benzene is not an ingredient, we're
- [19] not adding this new ingredient with benzene. So
- [20] there's no reason to even consider there's a
- [21] possibility of a synergy.
- [22] Q Well, given the fact that benzene is
- [23] actually in the cigarette smoke, why would you not
- [24] want to know if the new ingredient had an interaction
- [25] with something that you know to be in the cigarette

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[1] smoke?

[2] A Maybe I can answer that this way. As I said
[3] before, based on well-established models in the food
[4] industry, synergy of ingredients is not required in an
[5] evaluation. Second point also as I said, we do
[6] evaluate the smoke to include smoke chemistry for many
[7] of the product design changes and proposed
[8] ingredients. And when we evaluate the smoke
[9] chemistry, the smoke chemistry list includes the kinds
[10] of compounds that we just talked about.

[11] Q But sometimes that evaluation of the
[12] chemistry doesn't really involve a review of the
[13] literature; is that correct?

[14] A It it's a review of the chemistry, then --
[15] well, I'm interpreting that as doing a smoke chemistry
[16] study, but if there's already enough information in
[17] the literature that was sufficient to answer any
[18] concerns we had in reviewing an item, then it would be
[19] sufficient. If it is sufficient, then we don't need
[20] testing. But wherever we do need testing, we do it.
[21] And when we do smoke chemistry, we have a
[22] comprehensive list that we always run.

[23] Q You have a comprehensive list that you
[24] always run?

[25] A To include the items that I just listed for

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[1] ingredient -- and I said this, I think, a couple of
[2] questions ago -- you use a Reference cigarette that
[3] has no ingredients on it, or almost no ingredients on
[4] it. That's the basic Reference cigarette. And so you
[5] would do the smoke chemistry on that cigarette.

[6] And then you also use that same Reference
[7] cigarette with no changes except having added the
[8] ingredient that you're testing, and then you look at
[9] that smoke chemistry. So now you can look at the
[10] smoke chemistry with and without the ingredient to see
[11] what the ingredient does to the smoke that you are
[12] asking about. And actually to go back to the
[13] synergism, that's the reason why we don't complicate
[14] it by having a lot of other ingredients in the test.

[15] Q But you do know it's possible that two or
[16] more of the additives and/or ingredients by themselves
[17] can have some kind of synergistic effect; you are
[18] aware of that, right?

[19] A That's a little complicated. Am I aware
[20] that's it's possible?

[21] Q Yes.

[22] A Anything, especially in science, is
[23] possible. So I'm aware that anything is possible.
[24] I'm not aware of any of these interactions having
[25] occurred.

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[1] you.

[2] Q In what way are those items included in your
[3] comprehensive smoke chemistry test?

[4] A In what way, in that we measure them.

[5] Q Measure how much of each of those substances
[6] are in the smoke?

[7] A Yes, that's correct.

[8] Q Do you measure how each of those substances
[9] interact with the new ingredient?

[10] A The ingredient was added to the cigarette.
[11] Smoke is a function of burning the cigarette. When we
[12] test a new ingredient, as I told you before, you would
[13] add it to a Reference cigarette, and so you would have
[14] the ability to compare the Reference cigarette with no
[15] ingredients on it to the test cigarette which has
[16] ingredient on it.

[17] Q So what you're saying is when you test and
[18] you use a Reference cigarette that contains basically
[19] no additives other than the one new ingredient, you
[20] are able to get a look at how that one new ingredient
[21] works with all the things that not additives?

[22] A Well, I think the first part of your
[23] question overlooks something, and maybe in clarifying
[24] that, that might be the answer to your question. The
[25] Reference cigarette -- when you design a test for

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[1] Q Well, because you never test for those
[2] interactions, correct?

[3] A We never test for those interactions. And I
[4] think most of the research in interactions tends to
[5] come up with no interaction results. But remember,
[6] that, likewise, testing ingredients in foods takes the
[7] same approach. And I think it has been a
[8] well-established, well-worked out, well-defined by
[9] many experts approach to evaluating ingredients.

[10] Q So long as you are dealing with a food,
[11] correct?

[12] A No. I think it's a well-established
[13] approach. It has been established in the food
[14] industry. It's been established in other consumer
[15] products and applied to those, and I think it is
[16] generalizable.

[17] Q You think it's generalizable to drugs?

[18] A As I said to you, the end formulation and
[19] review of drugs, I'm not that familiar with, but I
[20] would guess that in talking about the flavor additives
[21] and things like that, it may very well be applied
[22] there as well, but I'm not that familiar with.

[23] Q Well, not only are you not that familiar
[24] with it, you just don't know, right?

[25] A I think that's fair. I don't know exactly

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[1] how it's done in the drug industry.

[2] Q Now, as far as testing new products, have
[3] you been involved in any testing of new products?

[4] A Yes, I do have responsibility to test new
[5] product designs.

[6] Q And what has been your involvement in
[7] testing new design?

[8] A Well, similar kinds of testing as we do for
[9] a new additive, any proposed new product design,
[10] whether it's a change to the conventional cigarette or
[11] a non-conventional approach we are involved in
[12] reviewing. And a lot of my time in the last few years
[13] has been spent on the Electrically heated cigarette.

[14] Q And what have you done?

[15] A Reviewed the product; made sure that any
[16] ingredients that were used were acceptable; looked at
[17] the design itself; done things like the smoke
[18] chemistry that we are talking about and other smoke
[19] tests, inhalation tests. Things like that.

[20] Q Does the electrical cigarette remove any of
[21] the carcinogenic components of cigarette smoke?

[22] A They are very much reduced.

[23] Q Which ones are reduced, and by how much?

[24] A Well, I can't be complete off the top of my
[25] head, but I can give you part of the story. The

[1] Q Now, when you look at tar content for the
[2] Reference cigarettes that you are talking about,
[3] that's equivalent to the tar content in a Marlboro
[4] Lite; is that correct?

[5] A I can't remember exactly what a Marlboro
[6] Lite's tar delivery is, but that should be close. But
[7] it's basically -- to be accurate, let me just say that
[8] the tar delivery of 1R4F is nine milligrams.

[9] Q Assuming that it's roughly the same as the
[10] Reference cigarette that you tested again, this new
[11] product, assuming that it's roughly equivalent to the
[12] tar delivery of the Marlboro Lite, that means that the
[13] Marlboro Lite contains many, many times more of these
[14] carcinogenic components than the new product, correct?

[15] A You can't take the tar delivery and make an
[16] assumption about what it means for individual items.

[17] Q Well, let's, for example, take the
[18] benzo(a)pyrene, you said it reduces the benzo(a)pyrene
[19] by 97 percent or maybe even more.

[20] A Correct.

[21] Q So that means that when you compare a
[22] Marlboro Lite to this cigarette, this new product,
[23] that the Marlboro Lite contains approximately 33 times
[24] the amount of benzo(a)pyrene than this new cigarette
[25] does, correct?

[1] electrical heated cigarette has been tested compared
[2] to this Reference cigarette that we talked about
[3] before, the University of Kentucky Reference cigarette
[4] called the 1R4F, which is similar to the US
[5] marketplace in tar delivery, and when you compare this
[6] electrically heated cigarette to that Reference
[7] cigarette, over -- well, almost two thirds of our
[8] chemistry testing list is reduced per cigarette by
[9] over 90 percent. And the polyaromatic hydrocarbons
[10] are reduced by over 90 percent. I think many of them
[11] by over 95 percent. Specifically, benzo(a)pyrene is
[12] reduced by over, I think, 97 percent, but I know that
[13] we are not totally sure exactly how much it reduced,
[14] because it gets so low that it's difficult to
[15] quantitate it, and we are working on trying to
[16] quantitate it at lower levels.

[17] But in some of the prototypes for
[18] aminobiphenyl was the ability to quantitate. And
[19] 2-naphthylamine as well. Benzene is reduced by over
[20] 90 percent. Carbon monoxide -- there are other things
[21] besides carcinogens on the list. Carbon monoxide is
[22] reduced by over 90 percent. The nitrosamines tend to
[23] be reduced by over 80 percent. I think that's not the
[24] complete list, but that's what comes to mind at the
[25] moment for reductions.

[1] A I don't know what the level is in Marlboro
[2] Lite is.

[3] Q If we assume that the level in Marlboro
[4] Lites is the same as the as the level in this
[5] Reference cigarette, then that would mean that the
[6] Marlboro Lite has about 33 times more times
[7] benzo(a)pyrene than this new product does, correct?

[8] MR. BHATIA: Object to the form.

[9] A Yeah. The Reference with the 97 percent
[10] reduction, that means that on a per cigarette basis,
[11] the Reference cigarette has about, yeah, about
[12] thirtyish times more benzo(a)pyrene or a per cigarette
[13] delivery. So if you wanted to assume that it was like
[14] another brand, that number would be correct.

[15] Q And for the benzene you said it was about
[16] 90 percent, so it would be 30 times more benzene in
[17] the commercial product using Marlboro Lite an example?

[18] A No. If it's about 90 percent reduced, that
[19] would be about 10 times.

[20] Q I'm sorry. Your math is right. I
[21] apologize. Ten times more benzene in the commercial
[22] product that's sold now than in this new product,
[23] correct?

[24] A If this commercial product you're talking
[25] about is the same as the 1R4F, that would be correct.

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[1] Q I'm using the Marlboro Lite as an example,
[2] because the expert from Philip Morris a few weeks ago
[3] told me it would be roughly equivalent to that, the
[4] Marlboro Lite in tar delivery?

[5] A Okay. That may be the case, but I don't
[6] know that for a fact.

[7] Q Now, this new product that you tested, what
[8] kinds of tests did you run?

[9] A Well, we have done many analyses of various
[10] parts and ingredients, parts of the lighter as well as
[11] the ingredients of the lighter or of the cigarette.
[12] Whether it's just a chemical analysis to confirm the
[13] identity, getting disclosures from vendors about what
[14] materials were used, reviewing the literature on the
[15] individual items, reviewing the regulatory status of
[16] the individual items, heating the materials or the
[17] parts or pyrolyzing them to see what kind of materials
[18] might come off of them in those environments.

[19] Q And what is the nicotine content of the new
[20] product?

[21] A Excuse me, if I could finish.

[22] Q Certainly.

[23] A And then after that, taking the entire
[24] product and smoking it according to standard
[25] conditions, likewise the 1R4F, and doing comparisons

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[1] achieves that by heating the cigarettes only when they
[2] are being puffed on, and just heating one spot of it,
[3] and the health turns off after two seconds. That's
[4] really the technology. The decreases in the chemistry
[5] come from the low temperature of the heat.

[6] Q When was this product first started? When
[7] did development first start on this product if you
[8] know?

[9] A Research. It depends, I guess, when you
[10] define the beginning of development. About the time I
[11] arrived, I know was the beginning of the serious final
[12] development of it, 1993, but a lot of work had
[13] preceded that.

[14] Q Do you know when the work started on that
[15] product?

[16] A No, I'm not really sure. I know that
[17] conceptually the concept of heating tobacco by various
[18] means may go back as much as 20 years.

[19] Q You know RJR had a product they introduced
[20] in 1980, correct?

[21] MR. BHATIA: When?

[22] MR. HOAG: 1980.

[23] Q Are you aware of that?

[24] A I believe you're talking about Premier, and
[25] I thought it was the late 1980's.

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[1] of the smoke chemistries on this chemistry list as
[2] well as on in vitro assays, specifically, genotoxicity
[3] and cytotoxicity, and also laboratory rat inhalation
[4] study.

[5] Q What is the nicotine content of the new
[6] product you are referring to?

[7] A It's about .2 or .3.

[8] Q So is this new product basically a nicotine
[9] delivery device?

[10] MR. BHATIA: Object to the form.

[11] A This new product is a cigarette, and the
[12] difference in it is that its heat source is not a
[13] burning tobacco, but electrically heated blades.

[14] Q Electrically heated what?

[15] A Blades.

[16] Q Is there any tobacco in the product at all?

[17] A The cigarette is totally of all conventional
[18] materials in it. It is tobacco, yes.

[19] Q Would it have been possible to remove more
[20] of the nicotine than they did?

[21] A The question, it's hard to answer, because
[22] the way you're saying remove the nicotine, it wasn't
[23] — nothing was necessarily removed. There's no
[24] removal device. The cigarette was designed to have
[25] low odor, no ash, and no side stream smoke, and it

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[1] Q Do you know whether or not this product was
[2] developed in response to RJR's development of the
[3] Premier product or other products that heat tobacco?

[4] A I don't know whether that would have been
[5] the case or not.

[6] Q Do you know whether they began the
[7] development process for this product 20 years ago when
[8] it first became something that was discussed or
[9] researched in the development of a product that would
[10] heat tobacco?

[11] A I'm sorry. You started you said when they
[12] began, I wasn't sure what you were talking about.
[13] Could you ask the question again.

[14] Q When I say that, I mean Philip Morris, but
[15] I'll repeat it. Do you know when Philip Morris first
[16] began to develop this product, 20 years ago or 10
[17] years ago or when they first began to develop it?

[18] A Well, as I said, you know, the work had been
[19] done probably as much as 20 years ago. And depending
[20] on what you mean by development, when does research
[21] end and development of a defined product begin, again,
[22] I think the serious development of something that
[23] looked like this product and had the technology and
[24] capabilities to make something that was marketable
[25] like this probably started around the time I arrived.

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[1] a little bit before I arrived in '93.

[2] Q Who developed the technology if you know?

[3] A Well, there are various technologies. Some
[4] of them were simply things like the miniaturization of
[5] battery sources, which wasn't possible until more
[6] recently as batteries have gotten smaller and more
[7] powerful. Some of that was just a matter of waiting
[8] until other industries developed that technology.

[9] Some of the technology such as the blades
[10] that provide the heat source were developed by Philip
[11] Morris, and we own the patent rights to these
[12] materials.

[13] Q When was that developed, the blade?

[14] A Probably mostly over the last five years.

[15] Q When did the miniaturization of batteries
[16] come into existence such that Philip Morris would be
[17] able to benefit from that?

[18] A I think probably in the same time period.
[19] I'm not an expert in this area, but I think a good
[20] example is to just look at the timetable over which
[21] cell phones have gotten smaller and smaller, and you
[22] can see maybe ten years ago, the size of the cell
[23] phone versus what it was five years ago, versus now.

[24] Q Do you have any personal knowledge about
[25] when they first developed miniaturization of a

[1] people or not if people smoked it as frequently as
[2] they smoke commercial cigarettes, correct?

[3] MR. BHATIA: Object to the form.

[4] A The data that we have does not allow me to
[5] speak to the safety of the product or relative safety
[6] of the product that you're asking.

[7] Q Does anybody have data like that, data that
[8] would allow them to speak to whether or not the
[9] product safer than other products that you know of?

[10] A To answer your question, first you would
[11] have to define what kind of data would be sufficient.

[12] Q Have you done that?

[13] A It wouldn't be our -- it wouldn't be
[14] possible for us to define that, because if such a
[15] determination of safety was going to be made, it would
[16] probably be made by the government, and they would
[17] have to define what tests they thought were adequate
[18] to make that determination.

[19] Q Well, you would agree that the only thing
[20] that's really safe regarding smoking is not to do it,
[21] correct?

[22] A No. I think that when we started, we had
[23] talk about that, and I told you that I thought
[24] anything was okay in moderation.

[25] Q Do you know anything about whether or not

[1] battery?

[2] A I can only remember seeing batteries that
[3] are of the current size, probably got to that size
[4] around 1994 or 5. There were a little bit bigger
[5] before that.

[6] Q Is it safer than the commercial products
[7] that's sold now?

[8] A I'm sorry. When you started, the speaker
[9] kicked out.

[10] Q Is this product safer than the currently
[11] sold commercial products, cigarettes?

[12] A As I described to you in response to your
[13] question before, the kinds of testing that we've done.

[14] Q I'm asking you is this product safer?

[15] A I haven't gotten the data to tell you
[16] whether that's the case or not. I can tell you that
[17] the testing we have done shows the kind of reductions
[18] we talked about in the chemistry. And I can tell you
[19] that the biological testing shows large reduction in
[20] measured biological activity, in bacteria in cultures,
[21] in mammalian cells in culture, and in rats in the
[22] laboratory. But can I tell you what that means in
[23] terms of your question regarding safety, no, I can't.

[24] Q So you don't know whether or not the product
[25] would result in the deaths of hundreds of thousands of

[1] cigarette smoking is addictive?

[2] A No, that's not my area. I don't work in the
[3] area of addiction.

[4] Q Do you know anything at all about whether or
[5] not Philip Morris adds ammonia to its products?

[6] A I know we talked before about ingredients,
[7] and I mentioned to you that ammonia is not. When we
[8] were talking about ammonium hydroxide being an
[9] ingredient, I said ammonia was not.

[10] Q So are you saying you know ammonia is not
[11] added to cigarettes?

[12] A That's correct. Ammonium hydroxide is
[13] added, or has been added. Again, before I told you
[14] that I wasn't sure which list had which items on it
[15] and whether it's still there or removed or whatever,
[16] but probably ammonium hydroxide, but not ammonia, and
[17] some other ammonia like compounds, like diammonium
[18] phosphate.

[19] Q Any other ammonia like additives other than
[20] diammonium phosphate, ammonia hydroxide that are added
[21] to cigarettes that you know of?

[22] A Yes. They are probably one or two. Let me
[23] think or a second. Urea is another one, and you can
[24] add that to the list from before when you asked me
[25] what was on the list of additives.

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[1] Q U-R-E-A?
[2] A U-R-E-A.
[3] Q Well, what's that?
[4] A It's a small molecule that's close in
[5] structure to ammonia. It's has ammonia, the nitrogens
[6] and the hydrogens from ammonia in it.
[7] Q Any other substances that are like ammonia
[8] or have ammonia in it that are added to cigarettes?
[9] A It just came to me. The last one I think
[10] probably would be ammonium bicarbonate. And I think
[11] that's probably it.
[12] Q And if you know, why are those added to
[13] cigarettes?
[14] A Again, this is outside of my area of
[15] expertise. From what I understand, some of them are
[16] processing aides, some of them are flavorants.
[17] Q Do you know why they are added to
[18] cigarettes, or are you just guessing?
[19] A I don't know it as far as my technical
[20] expertise, but I have been told that it's for
[21] processing aides and for flavorants.
[22] Q You have no personal knowledge of why the
[23] ammonia or ammonia like products are added to
[24] cigarettes; is that correct?
[25] MR. BHATIA: Object to the form. Asked and

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[1] a list is required either to comply with a regulatory
[2] requirement or a request for information, for example,
[3] in a court case.
[4] Q And who is David Williams?
[5] A David is a chemist in Product Integrity.
[6] Q What did he tell you?
[7] A Basically what I told you my understanding
[8] was that we have some ammonia like compounds that are
[9] used as processing aides or flavors, and the -- he has
[10] more detailed knowledge, but that's the most accurate
[11] I can pass it on.
[12] Q That's all that you actually recollect that
[13] David told you?
[14] A Yes.
[15] Q Your knowledge about ammonia and why it's put
[16] in cigarettes is based on what David told you?
[17] A And I said that's the person I probably
[18] talked to the most. I have talked with other people
[19] about it as well. And I guess in more detail when
[20] it's used as a processing aide, it's typically in the
[21] manufacture of sheet material.
[22] Q And how do you know that?
[23] A From discussions with David and other
[24] people. We have -- let's see, probably with Dick Uhl.
[25] Q Who is that?

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[1] answered.
[2] Q Is that correct?
[3] A If no personal knowledge means do I have
[4] firsthand understanding, no, I have no personal
[5] knowledge. If personal knowledge means have I heard
[6] people say why it's been added, then as I told you of
[7] my understanding from what I've heard people say is
[8] that it's as a flavorant or as a processing aide.
[9] Q Have you read any internal documents that
[10] discuss ammonia or ammonia like products added to
[11] cigarettes?
[12] A Well yes, as I told you, there are some
[13] ingredients that are ammonia like compounds, and since
[14] we can deal with the review of ingredients and have to
[15] provide a list to Health and Human Services every year
[16] and list all the ingredients, we would, of course,
[17] have to deal with documents which talk about what we
[18] are using at the moment.
[19] Q Who has discussed with you ammonia and its
[20] purpose for adding it to cigarettes?
[21] A Probably the person I talked to the most is
[22] an individual in my group, David Williams.
[23] Q And why did you talk to him about this?
[24] A He is responsible for pulling together
[25] ingredient information most often in situations where

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[1] A He works in R & D, and he's got a lot of
[2] expertise in the manufacture of sheet.
[3] Q You don't have any personal knowledge about
[4] the manufacture of sheet, do you?
[5] A I have toured the sheet manufacturing
[6] facilities, and again, to make ingredients' list, and
[7] if there are any new kinds of sheets that's are
[8] considered for manufacture, would have to be told how
[9] they are made and what ingredients are being used,
[10] such as, as I mentioned before, guar gum is an
[11] ingredient used in the manufacture of a different kind
[12] of sheet.
[13] Q How frequently do you tour the sheet
[14] manufacturing unit?
[15] A Just once, to get an idea.
[16] Q Just once?
[17] A Yes.
[18] Q What was the one you toured?
[19] A There are two of them, and I toured them
[20] each once. One is called the BL plant. It's here in
[21] Richmond, a little north of the manufacturing center.
[22] And the other one is Park 500, southeast of Richmond.
[23] Q And how long were you there when you toured
[24] each of these places?
[25] A Gosh, I would guess maybe a couple of hours.

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[1] Q How long ago did you do these tours?

[2] A Either in 1993 or 1994 when I first arrived.

[3] Q And did you actually observe ammonia being

[4] added to the cigarettes or the sheets?

[5] MR. BHATIA: Object to the form.

[6] A I think I told you before ammonia is not

[7] added.

[8] MR. BHATIA: John, Rick does have to go now.

[9] MR. HOAG: Well, I'm not finished. I'm not

[10] sure what we do. Why don't you come up with some

[11] suggestions. He can stay or he can come back

[12] again if he doesn't have any more time. I'm not

[13] finished, and I have to stop now.

[14] MR. BHATIA: I guess then we will stop. You

[15] are not willing to give us an estimate of how

[16] much more time you need.

[17] MR. HOAG: What do you mean not willing to

[18] give you an estimate. You said he has to stop

[19] right now. If you have more time, tell me.

[20] MR. BHATIA: He doesn't. We told you 12:15.

[21] Do you want to try to continue it later today?

[22] What do you want to do? You are not really being

[23] cooperative.

[24] MR. HOAG: This is baloney. Are you just

[25] trying to annoy me now? I guess you are not

[1] you'll be done with the other guy?

[2] MR. HOAG: I don't know. It depends on what

[3] he as to say. You guys only gave me a sentence

[4] from him, so I really don't know what he has to

[5] say.

[6] MR. BHATIA: The witness has to go to his

[7] daughter's graduation. We are willing to bring

[8] the witness back. The preference would be to

[9] bring the witness back today. And I'm going to

[10] let the witness go to that event which we had

[11] told counsel about this morning, and counsel for

[12] the plaintiffs and I will try work out an

[13] agreeable time to bring Mr. Solana back so we can

[14] complete the deposition today.

[15] MR. HOAG: Why don't we try 4:30.

[16] MR. BHATIA: Rick, can you be back at 4:30?

[17] THE WITNESS: Sure.

[18] MR. BHATIA: Just to be safe, why don't we

[19] just say 5:00?

[20] MR. HOAG: Well, you can say that but I'd

[21] rather shoot for 4:30, if he can be back at 4:30.

[22] Hopefully, the other witness I can get done in

[23] three hours. I would like to.

[24] MR. BHATIA: Okay.

[25] MR. HOAG: If we start at 1:30, I might be

[1] being cooperative. I called you guys at 9:00.

[2] You weren't there. You gave me the wrong phone

[3] number. You wait for 15 minutes because you gave

[4] me the wrong phone number.

[5] MR. BHATIA: Rick, you can go ahead and go.

[6] MR. HOAG: You gave me nothing but a

[7] sentence on this witness, and I'm not being

[8] cooperative. What nonsense.

[9] MR. BHATIA: Well, we obviously disagree.

[10] The witness, we told you his daughter is

[11] graduating.

[12] MR. HOAG: All this time, I could have been

[13] asking more questions.

[14] MR. BHATIA: Believe me, I've not objected

[15] much, although I certainly could have.

[16] MR. HOAG: I know you could have.

[17] MR. BHATIA: I'm willing to bring the

[18] witness back. Let's just talk about when you

[19] want to do it.

[20] MR. HOAG: Let's do that. When did you

[21] bring him back today?

[22] THE WITNESS: 2:30.

[23] MR. HOAG: I don't think I'll be done with

[24] the other guy by 2:30.

[25] MR. BHATIA: Well, okay. When do you think

[1] able to do that.

[2] MR. BHATIA: I just don't want the witness

[3] waiting around. 4:30 is fine is that's when

[4] you'll finish by.

[5] MR. HOAG: Well, I can't guarantee it, but

[6] I would like to try.

[7] MR. BHATIA: Okay. Well, we will

[8] accommodate your interests and your wishes.

[9] MR. HOAG: Well, okay. You will accommodate

[10] my wish that he actually be here at 4:30, and I

[11] can get done with the next one in three hours.

[12] MR. BHATIA: That's right.

[13] MR. HOAG: There is need in going on. Let's

[14] just do that. I'm be back on at 1:30 for the

[15] next witness.

[16] MR. BHATIA: That's perfectly fine. We will

[17] see you at 1:30. Why didn't you give me your

[18] phone number in case we have a problem with the

[19] connection again.

[20] MR. HOAG: Area code (954) 434-7734.

[21] MR. BHATIA: Okay. And I know the witness

[22] appreciates your accommodating his ability to go

[23] to the graduation.

[24] MR. HOAG: Okay. Have good time at the

[25] graduation.

<p>Page 105</p> <p>[1] MR. BHATIA: He's already gone so that he</p> <p>[2] doesn't miss it.</p> <p>[3] MR. HOAG: Good. I'm glad he left, because</p> <p>[4] he needed to do go. Okay.</p> <p>[5]</p> <p>[6] (Whereupon the deposition was suspended</p> <p>[7] until 4:30 p.m.)</p> <p>[8]</p> <p>[9] (Plaintiff's Deposition Exhibit 1 is</p> <p>[10] marked.)</p> <p>[11]</p> <p>[12] Q Dr. Solana, is this your resume or CV?</p> <p>[13] A Yes, it is.</p> <p>[14] Q And referring to your current job as a</p> <p>[15] principal scientist, what is your salary for that</p> <p>[16] position?</p> <p>[17] A Correction. This is a CV as of</p> <p>[18] December 1996, and I think we had mentioned to you</p> <p>[19] earlier today is the one that thing that was missing</p> <p>[20] was my current position as of last year.</p> <p>[21] Q Okay. You're right. I just got finished</p> <p>[22] with a separate deposition, and it kind of slipped my</p> <p>[23] mind. What is your current position?</p> <p>[24] A Director of Product Integrity.</p> <p>[25] Q How long have you held that?</p>	<p>Page 106</p> <p>[1] A Since April of last year, April of '97.</p> <p>[2] Q And what is your current salary?</p> <p>[3] A It's approximately \$130,000.</p> <p>[4] Q Per year?</p> <p>[5] A Yes.</p> <p>[6] Q And is there any other form of compensation</p> <p>[7] that you receive?</p> <p>[8] A Stock options, profit sharing.</p> <p>[9] Q Any bonuses?</p> <p>[10] A Yes, bonus.</p> <p>[11] Q Did you receive a bonus for last year?</p> <p>[12] A Yes, I did.</p> <p>[13] Q How much was your bonus?</p> <p>[14] A Approximately \$50,000.</p> <p>[15] Q And aside from the bonus and the yearly</p> <p>[16] salary, and the stock options, did you receive any</p> <p>[17] other compensation?</p> <p>[18] A I think we said the salary, bonus, stock</p> <p>[19] options, and profit sharing.</p> <p>[20] Q What was your profit share compensation for</p> <p>[21] last year?</p> <p>[22] A Approximately \$15,000.</p> <p>[23] Q Stock options, do you own stock options now?</p> <p>[24] A Yes, I do.</p> <p>[25] Q Approximately how many shares?</p>
<p>Page 107</p> <p>[1] A Oh gosh, very roughly, 5,000. I'm just not</p> <p>[2] sure.</p> <p>[3] Q And of those 5,000 that you hold now, are</p> <p>[4] any of them worth more than the amount that you would</p> <p>[5] have to pay for them if you wanted to exercise your</p> <p>[6] option?</p> <p>[7] A There's a good chance that they are not.</p> <p>[8] Q You just don't know one way or the other, or</p> <p>[9] do you know?</p> <p>[10] A No, I'm not sure. I'm sure that many of</p> <p>[11] them are not. I'm not sure if any of them are above</p> <p>[12] the current value.</p> <p>[13] Q Have you exercised the option on any of the</p> <p>[14] shares to where you actually have made a profit or</p> <p>[15] owned shares other than just options?</p> <p>[16] A I exercised an option once, yes.</p> <p>[17] Q And did you receive money or did you just</p> <p>[18] purchase the shares?</p> <p>[19] A I take that back. Correction. I exercised</p> <p>[20] them once to receive money. That was the one I was</p> <p>[21] mentioning.</p> <p>[22] Q Right.</p> <p>[23] A And then there was one that after three</p> <p>[24] years had to be exercised, and so I had that in</p> <p>[25] shares.</p>	<p>Page 108</p> <p>[1] Q And how many shares do you own currently of</p> <p>[2] Philip Morris stock?</p> <p>[3] A I guess I was counting those that were</p> <p>[4] exercised in the estimate of 5,000. Those might be</p> <p>[5] something like, I think, a little short of 2,000.</p> <p>[6] Q And how much money did you receive when you</p> <p>[7] actually received money when you exercised the stock</p> <p>[8] option?</p> <p>[9] A About \$50,000 after taxes.</p> <p>[10] Q And now referring to the portion of your</p> <p>[11] resume that has Publications on it -- I'm not sure</p> <p>[12] what page it is on your resume -- the article authored</p> <p>[13] by you as first author and published in 1986 --</p> <p>[14] A Yes.</p> <p>[15] Q -- the title is Estimation and analysis of</p> <p>[16] the concentration-response surfaces associated with</p> <p>[17] multiple agent combinations.</p> <p>[18] A Yes.</p> <p>[19] Q What was that research about?</p> <p>[20] A That work came out of my Ph.D. thesis, and</p> <p>[21] it was using cells and culture after exposure to</p> <p>[22] different agents, some chemicals and some irradiation</p> <p>[23] to find out whether the different agents would be just</p> <p>[24] additive or interactive, similar to your term</p> <p>[25] synergistic or antagonistic.</p>

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- [1] Q And what did you find out?
- [2] A That all of these agents were additives when
- [3] interpreted on the classical theories of evaluating
- [4] activity, which is by the concept of isoboles and dose
- [5] addition.
- [6] Q By additive what do you mean?
- [7] A There was no antagonism or synergism.
- [8] Q Have you ever done any research where you
- [9] actually showed any synergism?
- [10] MR. BHATIA: Object to the form.
- [11] A Let me try to run through it in my mind for
- [12] a second. I can't recall a result that was ever above
- [13] the dose additive.
- [14] Q What was the purpose of doing that research
- [15] to find out if there was this result; why did you do
- [16] it?
- [17] A To evaluate largely the capability of this
- [18] method of static modeling called response surface
- [19] modeling to see if it could properly characterize the
- [20] results from the studies.
- [21] Q I guess I'm not really -- I know you
- [22] answered the question, but I guess I just didn't
- [23] totally understand it. The purpose of doing this
- [24] research -- and I am specifically referring to the one
- [25] in 1986 -- Estimate analysis of the

- [1] treatment.
- [2] Q So one time it would be important to look
- [3] and see if there is any synergy between substances is
- [4] to optimize treatment, correct?
- [5] A To optimize certain kinds a treatment, yes.
- [6] Q Are you familiar with the fact that radon
- [7] and cigarette smoke when combined have a synergistic
- [8] effect as far as disease causation is concerned?
- [9] A No, I'm not familiar with that literature.
- [10] Q Have you ever heard that prior to the time I
- [11] just mentioned it?
- [12] A I have heard that once or twice, but I'm not
- [13] that familiar with the literature.
- [14] Q Hypothetically, if it's true that radon and
- [15] cigarette smoke when combined have a synergistic
- [16] effect, meaning people are much more likely to
- [17] contract lung cancer if they are exposed to both radon
- [18] and cigarette smoke, would that be a significant
- [19] finding?
- [20] MR. BHATIA: Object to the form.
- [21] Q You can answer.
- [22] A Let me answer it and say that I am not sure
- [23] exactly what your meaning is of the term significance.
- [24] There could be statistical significance or some other
- [25] interpretation of the word. But my concern about

- [1] concentration-response surfaces associated with
- [2] multiple agent combinations was not actually to find
- [3] out if there was a synergistic effect, it was to find
- [4] out if a certain method of measurement was accurate?
- [5] A Yes. The non-method of measurement being
- [6] accurate, a method of modeling. So if you took these
- [7] different agents, and it was not primarily important
- [8] whether they were additive or synergistic or
- [9] antagonistic, but if you took them and had their
- [10] responses, could this statistical method of modeling
- [11] the results allow you to model it in such a way that
- [12] you could use the model to predict the results instead
- [13] of doing further experiments? Therefore, validating a
- [14] statistical mathematical model.
- [15] Q Is it ever important to find out if
- [16] substances are synergistic with one another?
- [17] A Is it ever important?
- [18] Q Yes.
- [19] MR. BHATIA: Object to the form.
- [20] A I would -- let me think for a second -- I
- [21] would say that there are certain kinds of chemical
- [22] therapy, particularly cancer chemotherapy, where they
- [23] intentionally combine agents for treatment that the
- [24] doctors are concerned about whether -- about how the
- [25] chemicals interact so that they can optimize their

- [1] whether it's a significant finding or not is as in any
- [2] science.
- [3] A single finding is not sufficient to
- [4] confirm that something is true or not. One to have
- [5] basic premises of science is that you would have to be
- [6] able to replicate the results in a meaningful way to
- [7] confirm that you've got something realistic.
- [8] And my second concern about it would be that
- [9] when I was doing the kinds of work that we were
- [10] talking about from this one article from the 1986, I
- [11] was looking at the literature regarding people's work
- [12] on interactions and looking at synergy, and one of the
- [13] basic and very common flaws I found was that people
- [14] would identify something as synergistic and come to
- [15] the conclusion that it was synergistic when in fact
- [16] they were using the wrong model, and more often than
- [17] not, they were incorrect in their interpretation.
- [18] Q (Inaudible) -- to find out whether or not
- [19] your interpretation is correct when you do find the
- [20] synergistic effect?
- [21] A I'm sorry, the beginning of your question
- [22] was cut off.
- [23] Q Is there a way to find out if your
- [24] interpretation is correct when you observe a
- [25] synergistic effect and think that you have found one?

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[1] A Well, the concern -- the flaw that I think
[2] exists in most scientists' logic is that their study
[3] design and their interpretation of their results is
[4] based on combining effects -- I'm sure this won't
[5] sound very clear, but if I do it by combining effects
[6] rather than combining doses, if you will. It's called
[7] effect addition versus dose addition. And effect
[8] addition can be very misleading. But to the layman in
[9] interactions, it seems very intuitive.

[10] So other than the few people who have
[11] focused on research and interactions, most people take
[12] this simple approach and make a misinterpretation.

[13] Q Have you focused on research of
[14] interactions?

[15] A When I did this early work for my Ph.D.,
[16] that was focussing on interactions.

[17] Q You know how to do that kind of research
[18] then, correct?

[19] A Yes, I do, at least in the areas that I have
[20] done it. It's been awhile since I worked in that
[21] area.

[22] Q You have never done that kind of research
[23] since you worked for Philip Morris, correct?

[24] A Correct. That was basic research.

[25] Q And I will just tell you there's been more

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[1] than one research article written about the
[2] interaction of radon and cigarette smoke. You can
[3] find it very easily on the Internet, for example.
[4] Now, if in fact there have been numerous, by that I
[5] mean more than five research articles about the
[6] interaction between radon and cigarette smoke that
[7] showed that if you smoke cigarettes and are exposed to
[8] radon, it exponentially increases your risk for lung
[9] cancer, that would be research that would go beyond
[10] being just basic research. It would be research that
[11] would have meaning for the health of people today,
[12] correct?

[13] MR. BHATIA: Object to the form.

[14] A I think I'm just stumbling over terminology
[15] with you. My definition of basic research is research
[16] that has to do with evaluating theory and coming up
[17] with the basic concepts rather than something that's
[18] closer to applied where you are developing a product
[19] or answering a very practical question.

[20] Q Right. For example, if someone was living
[21] in a house that had a certain level of radon, it would
[22] be very useful for them to know that if they smoke
[23] cigarettes and are exposed to the radon, they are
[24] increasing their health risks greatly by being exposed
[25] to both substances. That would be something that

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[1] would be useful for them to know now, correct?

[2] MR. BHATIA: Object to the form.

[3] A I would have to say that is not correct,
[4] because there are so many complexities in going
[5] from -- and again, I'm not really familiar. I have,
[6] as I told you, heard about this research a couple of
[7] times, but I'm not really that familiar with it -- but
[8] a lot of basic research, if you looked at it, it would
[9] be looking at the interactions in a specific model
[10] form. It may be cells in culture, or it may be by
[11] exposing laboratory rats in a specific way.

[12] Now, whether that type of exposure is at all
[13] similar to the kind of exposure you were just
[14] referring to about a person living in a home, whether
[15] it's laboratory rats or like people, and on and on,
[16] makes me have to say that no, that that information
[17] about what happened in that laboratory is not
[18] necessarily useful to the person in the home. I think
[19] it would have to be interpreted by a body of experts.

[20] Q Does Philip Morris ever do what you term to
[21] be basic research?

[22] A I'm not familiar with -- in the area of my
[23] responsibility and what I have been involved with, I'm
[24] not familiar with basic research that we have
[25] executed.

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[1] Q So you don't know whether Philip Morris does
[2] what you term to be basic research; is that correct?

[3] A No. I think there's some basic concept work
[4] out in the product development area that might be on
[5] very early concept, and I might term that basic
[6] research in the product development area.

[7] MR. HOAG: I don't have any other questions.
[8] Thank you very much for your time. And I'm
[9] ordering the same thing I ordered for the other
[10] deposition, the copy, the disk, and the
[11] miniscript. I assume he is going to read the
[12] depo?

[13] MR. BHATIA: Yes. I have just a few
[14] questions.

[15] EXAMINATION BY MR. BHATIA:

[17]

[18] Q Mr. Solana, my name is Vineet Bhatia. I'm a
[19] lawyer for Philip Morris. We met for the first time
[20] yesterday; is that right?

[21] A Yes.

[22] Q Now, based on your testimony this morning,
[23] it's my understanding that you joined Philip Morris in
[24] 1993?

[25] A Yes.

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[1] Q And before that time you were in the service
 [2] of this county in its armed services; is that right?
 [3] A Yes, in the air force and the army.
 [4] Q Am I right that you joined the air force
 [5] first in 1968?
 [6] A That's correct.
 [7] Q And you served this country for 25 years?
 [8] A Yes.
 [9] Q And you left the service as a lieutenant
 [10] colonel?
 [11] A Yes.
 [12] Q Mr. Solana, what was the highest rank you
 [13] achieved in the United States Armed Service?
 [14] A Well, as you said when I left, I was
 [15] lieutenant colonel.
 [16] Q Do you receive an honorable discharge?
 [17] A Yes.
 [18] Q And that was something you voluntarily
 [19] sought to do?
 [20] A Yes.
 [21] Q When you joined Philip Morris in 1993, was
 [22] one of your job responsibilities the testing of the
 [23] ingredients that Philip Morris adds to cigarettes?
 [24] A Yes, it is.
 [25] Q Does Philip Morris have a policy for testing

[1] voluntary agreement with the government called the
 [2] Scotch List, S-C-O-T-H.
 [3] Q And do other countries have similar lists?
 [4] A Yes, there are others.
 [5] Q Does Germany have a similar list?
 [6] A Germany is another country.
 [7] Q If a country such as Germany or the United
 [8] Kingdom bans the use of a specific ingredient, will
 [9] Philip Morris use that ingredient in any product in
 [10] the world?
 [11] A No. Our approach is that any regulation
 [12] that bans any ingredient, we will not use that
 [13] ingredient anywhere.
 [14] Q And just so the jury is clear, the lists
 [15] that you were describing the countries such as the
 [16] United Kingdom and Germany have, these are lists that
 [17] are specific for cigarettes?
 [18] A Yes, they are.
 [19] Q And they deal with the use of ingredients in
 [20] cigarettes?
 [21] A Yes, they do.
 [22] Q Now, the Philip Morris policy for review of
 [23] ingredients in the testing of ingredients, does that
 [24] policy apply every time a new ingredient is added to a
 [25] cigarette?

[1] the ingredients that are added to cigarettes?
 [2] A Yes, we do.
 [3] Q Can you give the jury an overview of that
 [4] policy?
 [5] A Well, the policy basically describes
 [6] evaluating proposed new additives or product design
 [7] changes, the reviews required of the literature for
 [8] that change, the evaluation of regulatory status and
 [9] testing that might be required.
 [10] Q When you reviewed the regulatory status of a
 [11] particular ingredient, is one of the things that you
 [12] and others at Philip Morris do is look at how other
 [13] countries treat particular cigarette ingredients?
 [14] A Yes, it is.
 [15] Q And can you tell the jury whether some
 [16] countries have specific approved lists of ingredients
 [17] that can be added to cigarettes?
 [18] A Yes, there are a number of regulations that
 [19] exist in various countries that have lists of approved
 [20] ingredients.
 [21] Q Does the United Kingdom, for example, have
 [22] such a approved list?
 [23] A Yes, they do.
 [24] Q What it called, sir?
 [25] A The current version of it -- it's a

[1] A Every time a new ingredient is proposed,
 [2] yes.
 [3] MR. HOAG: I'm going to object to the form
 [4] of the question, because there's no time frame to
 [5] this.
 [6] MR. BHATIA: Go ahead.
 [7] MR. HOAG: No time frame.
 [8] MR. BHATIA: Okay.
 [9] MR. HOAG: Are you talking about since the
 [10] company became a company or what?
 [11] MR. BHATIA: You can just object as to form.
 [12] I think that's the rule.
 [13] Q And does this policy also apply whenever
 [14] there is any change in the design of the cigarette?
 [15] A In design changes as well, yes, it does.
 [16] Q And you joined -- this policy, was it in
 [17] place when you joined Philip Morris?
 [18] A Yes, it was.
 [19] Q And did it predate your involvement at
 [20] Philip Morris?
 [21] A Well, that would be before my time. I
 [22] couldn't speak to that.
 [23] Q Now, based on this policy that you just
 [24] described for the jury, have you ever determined that
 [25] a new ingredient should not be added to Philip Morris

<p>Page 121</p> <p>[1] cigarettes?</p> <p>[2] A Yes, we have.</p> <p>[3] Q And did you make a recommendation to Philip</p> <p>[4] Morris management that that ingredient not be added?</p> <p>[5] A Yes.</p> <p>[6] Q Did Philip Morris follow your</p> <p>[7] recommendation?</p> <p>[8] A Yes, they did.</p> <p>[9] Q Has Philip Morris ever failed to follow your</p> <p>[10] recommendation that an ingredient not be added to</p> <p>[11] cigarettes?</p> <p>[12] A No, they haven't.</p> <p>[13] Q Now, I want to change subjects for just a</p> <p>[14] minute. The tobacco companies in 1986 disclosed a</p> <p>[15] list of ingredients added to cigarettes to the United</p> <p>[16] States government; were you aware of that?</p> <p>[17] A Yes, I am aware of it.</p> <p>[18] Q Can you tell the jury why they did that?</p> <p>[19] A Starting in 1986, the Department of Health</p> <p>[20] and Human Services was required to receive a list.</p> <p>[21] Q So was this something that the United States</p> <p>[22] Congress required the tobacco companies to do?</p> <p>[23] MR. HOAG: Object to the form of the</p> <p>[24] question unless he has personal knowledge.</p> <p>[25] MR. BHATIA: Could you please just object to</p>	<p>Page 122</p> <p>[1] form. I think that's the rule. I would</p> <p>[2] appreciate it if you would follow it.</p> <p>[3] MR. HOAG: I'm going to make whatever</p> <p>[4] objection I feel like making just like you guys</p> <p>[5] do, sometimes a speaking objection.</p> <p>[6] MR. BHATIA: I don't. I didn't. But its up</p> <p>[7] to you. You are the one who has to explain it to</p> <p>[8] the Judge.</p> <p>[9] MR. HOAG: I understand that.</p> <p>[10] MR. BHATIA: Let's keep going.</p> <p>[11] Q Was this something that the United States</p> <p>[12] Congress required the companies to do?</p> <p>[13] MR. HOAG: Same objection.</p> <p>[14] A It was required by law, yes.</p> <p>[15] Q And you are familiar with that law, aren't</p> <p>[16] you?</p> <p>[17] A Yes, I am.</p> <p>[18] MR. HOAG: I'm going to object to the last</p> <p>[19] question as leading, also vague and ambiguous.</p> <p>[20] Q Are you familiar with the law that required</p> <p>[21] the tobacco companies to disclose ingredients to the</p> <p>[22] Department of Health and Human Services?</p> <p>[23] MR. HOAG: Objection, leading, vague,</p> <p>[24] ambiguous.</p> <p>[25] A Yes, ma'am.</p>
<p>Page 123</p> <p>[1] Q And was that a law that was passed by the</p> <p>[2] United States Congress?</p> <p>[3] A Yes, it was.</p> <p>[4] Q To which department of the government did</p> <p>[5] the law require the tobacco companies to make</p> <p>[6] disclosure?</p> <p>[7] A As I said, to the Department of Health and</p> <p>[8] Human Services.</p> <p>[9] Q And did the tobacco companies make the</p> <p>[10] disclosure required by law?</p> <p>[11] A Yes.</p> <p>[12] Q Are the tobacco companies required to make</p> <p>[13] this disclosure every year to the Department of Health</p> <p>[14] and Human Services?</p> <p>[15] A Yes, they are.</p> <p>[16] Q Can you tell the jury some of the common</p> <p>[17] ingredients that appear on this list of cigarette</p> <p>[18] ingredients?</p> <p>[19] A Well, some of them are ones that we --</p> <p>[20] MR. HOAG: Objection, vague.</p> <p>[21] A Some of these ingredients are ones that</p> <p>[22] we've mentioned before, the various sugars, cocoa,</p> <p>[23] licorice, chocolate, things like that.</p> <p>[24] Q Are some of the ingredients that are added</p> <p>[25] to cigarettes, foods?</p>	<p>Page 124</p> <p>[1] A Yes.</p> <p>[2] Q And are some of the ingredients that are</p> <p>[3] added to cigarettes things that food manufacturers add</p> <p>[4] to foods?</p> <p>[5] A The list that we generated in 1993 was made</p> <p>[6] public in 1994, and that public list included the food</p> <p>[7] additive status and food additive approval status and</p> <p>[8] food generally recognized as safe status of those, and</p> <p>[9] almost the entire list was either of food or approved</p> <p>[10] food additives.</p> <p>[11] Q As part of the law that Congress passed</p> <p>[12] concerning the disclosure of cigarette ingredients,</p> <p>[13] did Congress require the Department of Health and</p> <p>[14] Human Services to report on any concerns that they</p> <p>[15] have with cigarette ingredients?</p> <p>[16] A Yes.</p> <p>[17] Q And are you aware, sir, of a single instance</p> <p>[18] when the Department of Health and Human Services</p> <p>[19] indicated that it had any concern with any ingredient</p> <p>[20] that the tobacco companies added to cigarettes?</p> <p>[21] MR. HOAG: Objection foundation.</p> <p>[22] A No, not that I can recall, no.</p> <p>[23] Q So to the best of your knowledge, sir, you</p> <p>[24] are not aware of a single instance where the</p> <p>[25] Department of Health and Human Services indicated that</p>

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[1] it had any concern with the ingredients that are added
[2] to cigarettes?

[3] MR. HOAG: Object to the form of the
[4] question. Leading, repetitive, vague, overly
[5] broad, ambiguous.

[6] Q You can go ahead. The Judge will overrule
[7] all of these.

[8] A I'm not aware of any report by Health and
[9] Human Services to Congress.

[10] Q In your work at Philip Morris, if the
[11] Department of Health and Human Services would have
[12] indicated that they had a concern, is that something
[13] in the ordinary course of business that you would have
[14] learned about?

[15] MR. HOAG: Object to the form of question as
[16] beyond his knowledge about what he would have
[17] learned about. It's also speculation.

[18] A I suppose it could be it -- could have
[19] occurred in either case. It's possible that we would
[20] have learned about it from either being told directly
[21] or from our Freedom of Information Act report. I
[22] suppose it's possible we would not have as well.

[23] Q It would be an odd law, wouldn't it, where
[24] the Department of Health and Human Services didn't
[25] tell the companies that they had the concerns but told

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[1] indicating that it had concern with the ingredients
[2] added to cigarettes?

[3] MR. HOAG: Object to the form of the
[4] question.

[5] MR. BHATIA: Just trying to get it right.
[6] You keep objecting. I am just trying to have a
[7] clean record.

[8] A Yes. To my knowledge there has been no
[9] report from Health and Human Services to Congress.

[10] Q Now, have the tobacco companies employed
[11] outside experts to review the list of ingredients that
[12] have been disclosed to do Congress?

[13] A Yes, we have.

[14] Q And in 1994 did those experts issue a
[15] report?

[16] A Yes.

[17] Q Have you reviewed that report?

[18] A Yes, I have.

[19] Q What was the conclusion of that report?

[20] A They concluded that the ingredients being
[21] used were not hazardous as used in cigarettes.

[22] Q Let me change subjects again. This morning
[23] you answered some questions about an electrical
[24] cigarette.

[25] A Yes.

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[1] someone else?

[2] MR. HOAG: Object to the form of the
[3] question, leading.

[4] MR. BHATIA: That's the first objection you
[5] have gotten right. You must have pulled out your
[6] Weinstein Manual on Evidence for that one. Go
[7] ahead.

[8] MR. HOAG: You're entertaining me at least.

[9] MR. BHATIA: Someone has to.

[10] A Would you repeat the question.

[11] Q Sure. It's hard I know when the lawyer
[12] objects. One of the things that you do in your work
[13] is you review the ingredients that Philip Morris adds
[14] to cigarettes, right?

[15] MR. HOAG: Object to the form of the
[16] question. It's leading. It's incredibly
[17] repetitive.

[18] MR. BHATIA: Keep objecting.

[19] MR. HOAG: Right. If you would just move on
[20] and get this over with -- asking the same thing
[21] over and over again -- it would be nice.

[22] A Yes.

[23] Q And in the course of that work, it has not
[24] come to your knowledge, sir, that the Department of
[25] Health and Human Services filed a report with Congress

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[1] Q Is that electric cigarette also referred to
[2] as Project Beta?

[3] A Yes, it is.

[4] Q And can you tell the jury what the goals of
[5] Project Beta were?

[6] A That electrically heated cigarette was
[7] designed to have no side stream smoke, low ash or no
[8] ash and low odor.

[9] Q Is that cigarette currently being tested by
[10] consumers?

[11] A Yes, it is.

[12] Q Does Philip Morris presently intend to
[13] introduce that cigarette into test markets?

[14] A Yes, based on successful results of consumer
[15] testing.

[16] Q I believe you testified earlier this morning
[17] that you did some testing of that cigarette; is that
[18] right?

[19] A Yes.

[20] Q And can you tell the jury the types of tests
[21] that you conducted?

[22] A Well, as I said earlier, it would be
[23] everything from evaluating the various ingredients and
[24] materials used in both the lighter and the cigarette,
[25] looking at the literature for information on these

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- [1] materials and ingredients, regulatory status of all
[2] these materials, and then for the cigarette as a whole
[3] in testing it compared to the University of Kentucky
[4] Reference 1R4F, which as I said, represents
[5] approximately the middle of the US marketplace in tar
[6] delivery. We have done valuations of smoke chemistry
[7] and various measurements of biological activity.
[8] Q Have you had occasion to present that
[9] testing data to outside scientists?
[10] A Yes, we have.
[11] Q Did you attend a meeting of the Society of
[12] Toxicologists in March of 1998?
[13] A Yes, March at the SOT.
[14] Q What is the commercial name of Project Beta?
[15] A Accord.
[16] Q And are you a member of the Society of
[17] Toxicologists?
[18] A Yes.
[19] Q At the annual meeting did you present any
[20] abstracts of the testing that you conducted?
[21] A Yes, I did.
[22] Q And did those abstracts contain the results
[23] of the tests that you performed?
[24] A Yes. They were summaries of the test
[25] results.

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- [1] A Well, of the entire list, more than
[2] 95 percent were of food or food additives.
[3] Q How many total additives were on that list?
[4] A Five hundred and ninety-nine.
[5] Q Thirty or so of the additives on the list
[6] were not food; is that right?
[7] A No.
[8] MR. BHATIA: Object to the form.
[9] A I can't remember exactly. I'm fairly
[10] confident it was less than ten or maybe much less than
[11] ten. However, some of those have regulatory approval
[12] status by other government agencies.
[13] Q What were those ten activities that are not
[14] food?
[15] MR. BHATIA: Object to the form. It
[16] misstates his prior testimony.
[17] A The only one I can recall would be one
[18] called methoprene, which is approved for use on
[19] tobacco by the EPA.
[20] Q That's methoprene?
[21] A M-E-T-H-O-P-R-E-N-E.
[22] Q You don't have any recollection to any of
[23] the others that are not food, right?
[24] A That's correct. I can't recall them right
[25] now.

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- [1] Q I don't want to go back through the test
[2] results that you testified to this morning, but was
[3] the information that you testified to this morning
[4] about the reduction of certain compounds like carbon
[5] monoxide, polyaromatic hydrocarbons, was that
[6] information reflected in the abstracts?
[7] A Yes, it is.
[8] MR. BHATIA: Thank you very much.
[9] MR. HOAG: One second. I might have a
[10] couple of questions.
[11]
[12] EXAMINATION BY MR. HOAG:
[13]
[14] Q You said that the additives, that cumulative
[15] list of additives that was provided to the government,
[16] almost everything on the list are food additives; is
[17] that correct?
[18] A Are food or food additives or food that the
[19] FDA or FEMA has approved as generally recognized as
[20] safe.
[21] Q Does that mean that there were some things
[22] on the list that were not food or food additives?
[23] A Yes.
[24] Q Which things were on the list that were not
[25] food or food additives?

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- [1] Q Are any of the additives used as poisons?
[2] A Not that I'm aware of.
[3] Q The list of additives that's provided to the
[4] government, that list does not tell the government
[5] which additives, which specific additives are in each
[6] brand of cigarettes, does it?
[7] A No, it does not.
[8] Q That is just a cumulation of the total
[9] number of additives in all the cigarettes, correct?
[10] A For the list we are talking about, which
[11] represents a combined list for five companies, it is a
[12] list of additives that's used for the brands for those
[13] companies, that is correct.
[14] Q So even the federal government doesn't know
[15] what particular additive is added to, for example,
[16] Marlboro, correct?
[17] A That's correct.
[18] Q Actually only Philip Morris knows that,
[19] correct?
[20] A Yes.
[21] Q If anyone was going to test the product for
[22] the synergistic effect that those additives have on
[23] all the carcinogenic components in the cigarettes, it
[24] would be Philip Morris that would have to do that kind
[25] of testing, right?

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[1] MR. BHATIA: Object to the form.
 [2] A It's not possible to answer that question,
 [3] because we talked about before, this idea of additives
 [4] and synergism -- I guess to restate -- I had said that
 [5] the idea of looking at synergism is something that not
 [6] only don't we do when we test typically, although we
 [7] have some data along those lines, we don't do it
 [8] because we modeled it after what we thought was a very
 [9] good model, which is the food industry approach.
 [10] Hence, when we talk about the list of approved food
 [11] additives, and that these items are approved food
 [12] additives, if you look at the FDA regulation on food
 [13] additives, you will see a list that's basically
 [14] similar. It's a list of approved additives, not
 [15] approved formulas for different brands.
 [16] Q What food are you aware of on that list by
 [17] the consumer of the food and intentionally inhaled
 [18] into the consumers' lungs numerous sometimes each day
 [19] for years, and that substance that is inhaled into the
 [20] lungs contains dozens of carcinogenic components, what
 [21] food has those qualities?
 [22] MR. BHATIA: Object to the form.
 [23] A I don't know of any food that meets that
 [24] description.
 [25] MR. HOAG: Thank you. I have no other

[1] COMMONWEALTH OF VIRGINIA,
 [2] CITY OF RICHMOND, to wit:
 [3]
 [4] I, Sherall W. Dementi, a Notary Public for
 [5] the State of Virginia at Large, do hereby certify that
 [6] the foregoing deposition of RICHARD P. SOLANA, Ph.D.
 [7] was duly sworn to before me at the time and place set
 [8] out in the caption hereto.
 [9] Further, that the transcript of the
 [10] deposition is true and correct, and that there was 1
 [11] exhibit filed with me during the taking hereof.
 [12] Given under my hand this 30th day of May,
 [13] 1998.
 [14]
 [15] _____
 [16] Sherall W. Dementi
 [17] Notary Public for the
 [18] State of Virginia at Large
 [19]
 [20] My Commission expires:
 [21] August 31, 1999
 [22]
 [23]
 [24]
 [25]

[1] questions. Thank you for your time. I have
 [2] already placed my order for the deposition.
 [3] MR. BHATIA: Thank you, John.
 [4]
 [5] (Deposition concluded at 5:15 p.m.)
 [6]
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[1] COMMONWEALTH OF VIRGINIA,
 [2] CITY OF RICHMOND, to wit:
 [3]
 [4] I, RICHARD P. SOLANO, Ph.D., do hereby
 [5] certify that I have read the foregoing pages of
 [6] typewritten matter numbered 1 through 133, and that
 [7] the same contains a true and correct transcription of
 [8] the deposition given by me on the 21st day of May,
 [9] 1998, with the exception of the noted corrections, to
 [10] the best of my knowledge and belief.
 [11]
 [12] _____
 [13] Date RICHARD P. SOLANO, Ph.D.
 [14]
 [15]
 [16] Subscribed and sworn to before me this ____
 [17] day of _____, 199__.
 [18] My commission expires _____
 [19]
 [20] _____
 [21] Notary Public
 [22]
 [23]
 [24]
 [25]